hbm+®

2022

Drug Trends & Strategic Insights

Emerging 2022 trends in drug claims, specialty drugs, biologics and biosimilars, as well as the impact of new therapies.

Drug Utilization Trends

Specialty Drugs

Non-Specialty Drugs

Emerging & Future Trends

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Introduction

Foreword

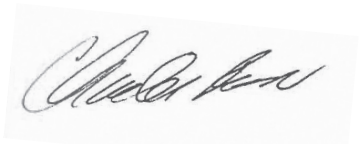
We are pleased to present our third annual HBM+ Drug Trends and Strategic Insights report. Much like the message at the beginning of last year's report, the challenges presented by the COVID-19 pandemic linger in our lives. While the world continues to reopen and work towards a "new normal," the emergence of new variants of concern reminds us how important it is to move forward. Unfortunately, it is not all in our rear-view mirror yet. The reality is that COVID-19 will still be with us for the foreseeable future, and in recognition of this, we have introduced a section on the COVID-19-related therapies being introduced to combat the virus.

In this year's report*, we provide the updates you are accustomed to seeing on trends related to specialty drugs, biologics, and biosimilars as well as the impacts of new, costlier, chronic disease therapies. We also updated last year's figures related to the use of virtual health care services (i.e., digital pharmacy). As you would suspect, the utilization rates have continued to rise, driven by the pandemic itself and changes to plan member behaviours.

New to this year's report is a deep dive on three drug classes that are seeing significant growth in terms of claimants and costs: diabetes, obesity, and cystic fibrosis (CF). For diabetes, we examine the overall expenditures on medications, glucose testing devices, and extended health care benefits and compare these against the results of non-diabetic claimants. In looking at obesity, we dispel the misunderstanding that it is a lifestyle choice and provide data to support an evolving perspective on how to improve coverage. Finally, as it relates to CF, we share an analysis that we conducted that looked at the impact of supporting therapies for CF patients which yielded some interesting results.

*Data for this analysis was conducted by IQVIA based on claims reported by HBM+.

We hope that you enjoy your read of the third edition of the HBM+ Drug Trends and Strategic Insights report. Our goal, as always, is to provide you with moments of reflection and meaningful insights that you can use to serve your clients and plan members now and into the future.



Charles Rosen, Senior Vice President and Managing Director, HBM+

Steve Laberge, Vice President-Quebec and Strategic Solutions, HBM+

Terminology

Term	Definition
Biologic drug	A drug product that is produced from living organisms.
Biosimilar	A biologic drug that is highly similar to another biologic drug known as the "originator biologic." Biosimilars are produced after patent expiry of the originator biologic.
Biosimilar penetration rate	Proportion of claims that were filled for biosimilar drugs.
Case management	A specialty pharmacy value-added service that coordinates patient-specific medical needs over the lifespan of their illness. These services may vary depending on the individual and specific illness but are designed to complement the patient's current health care team and journey.
Claimant	Any covered individual who has submitted at least one claim.
Extended health care	A benefit category that includes a variety of medical devices and services that do not relate to drug or dental benefits.
Gene therapy	A treatment method that involves modifying a patient's genes to treat a disease.
Generic penetration rate	Proportion of claims that were filled for generic drugs.

Term	Definition
Non-specialty drug	Refers to drug products that cost less than $10,000 per claimant. The cost is solely determined by its annual average claimant cost without dispensing fees.
Optical coherence tomography	A noninvasive imaging technology used to obtain high resolution cross-sectional images of the retina. The layers within the retina can be differentiated and retinal thickness can be measured to aid in the early detection and diagnosis of retinal diseases and conditions.
Originator biologic	Biologic drug that is first to market. Sometimes referred to as "reference biologic" or "innovator biologic."
Preferred pharmacy networks	Group of pharmacies that provide plan members with reduced drug claim costs when they fill their prescriptions at a participating pharmacy.
Retinal imaging	A test that takes a digital picture of the back of the eye. It shows the retina (where light and images hit), the optic disk (a spot on the retina that holds the optic nerve, which sends information to the brain), and blood vessels.
Specialty drug	Refers to drug products that cost $10,000 or more per claimant. The cost is solely determined by its annual average claimant cost without dispensing fees.
Specialty pharmacy	A pharmacy with expertise in managing complex diseases that require usage of high-cost biologics and other specialty drug products.
Total drug cost	Amount paid by the plan and patient. Includes drug costs, markups, and dispensing fees.

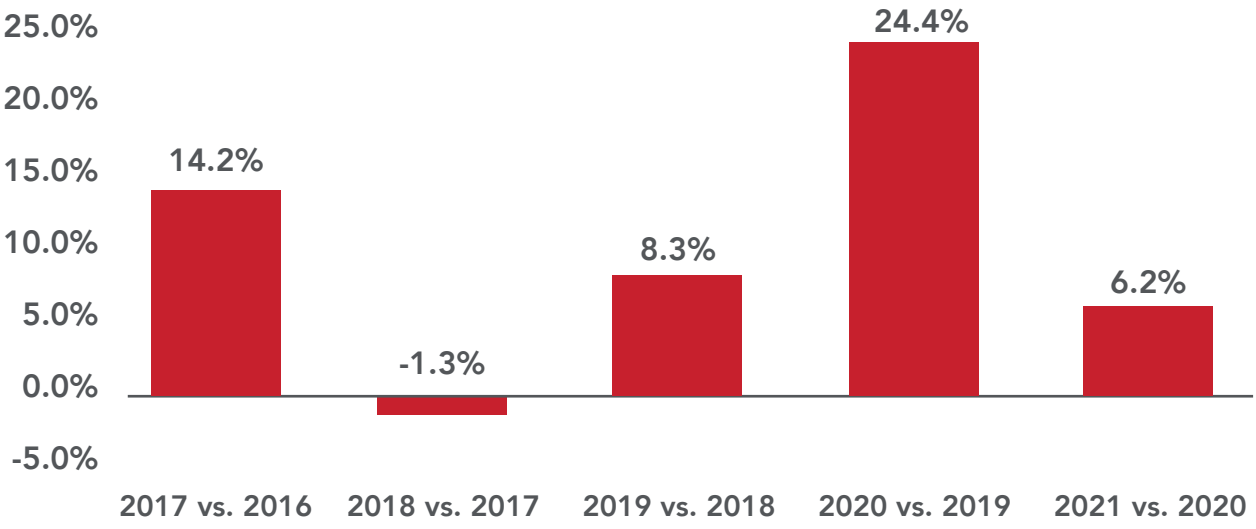
SECTION 2

Drug Utilization Trends

Overall Trends

Since 2017, the total drug costs adjudicated by HBM+ have risen from about $1.4 billion to $2.0 billion in 2021. At the same time, the number of claimants has increased from 1.9 million to 2.1 million. As outlined in Figure 2.1, there was a 6.2 per cent growth in total adjudicated drug cost between 2020 and 2021.

FIGURE 2.1 | Year-over-year growth in total adjudicated drug cost, 2017 to 2021

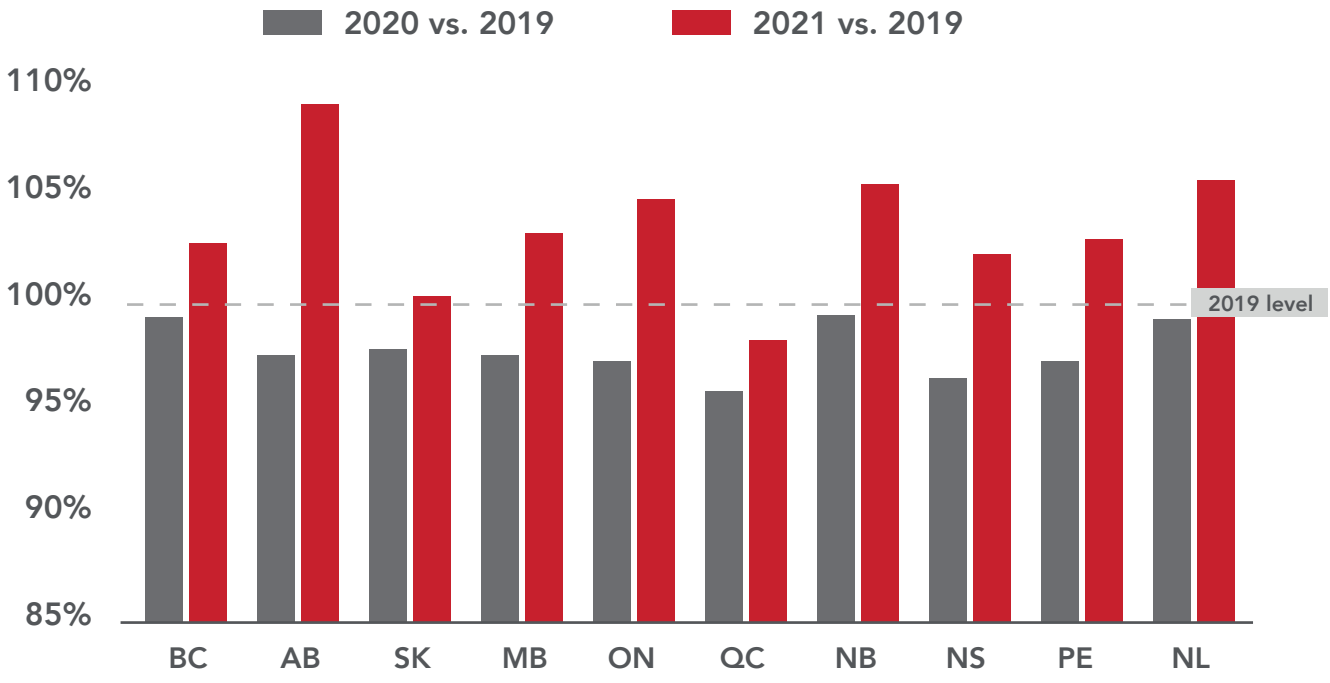


The number of overall drug claims adjudicated by HBM+ surpassed 30 million in 2021. The average drug cost per claim has grown steadily since 2017; except in 2020, when temporary COVID-19-related policies allowing shorter days' supply (i.e., 30 days) were implemented. This reduced the year-over-year average days' supply per claim across all provinces (Figure 2.2). Once these policies were lifted during the second half of 2020, the average days' supply normalized and subsequently resulted in a greater drug cost per claim in 2021 compared to 2020. In 2021, the average days' supply even surpassed the level set in 2019.

TABLE 2.1 | Total drug cost, claimants, total drug cost per claim, and number of claims per claimant, 2017 to 2021

Metric	2017	2018	2019	2020	2021
Total Drug Cost	$1.4B	$1.4B	$1.5B	$1.9B	$2.0B
Claimants	1.9M	1.8M	2.0M	2.1M	2.1M
Total Drug Cost per Claim	$64	$64	$66	$64	$68
Number of Claims per Claimant	11.9	12.2	11.9	14.5	14.2

FIGURE 2.2 | Relative difference in average days' supply per claim 2019/2020 and 2019/2021 by province



Note: Above 100% means the day supply per claim is higher than the 2019 level.

In addition to the differences in days' supply, the increased drug cost per claim in 2021 was driven by the greater share of claims from specialty (high-cost) drug products. Specialty products made up 0.64 per cent of the HBM+ claims in 2021–up 4.4 per cent compared to 2020. The average cost per claim for specialty products was nearly 64 times higher in 2021 than for their non-specialty counterparts.

TABLE 2.2 | Specialty share of claims by province, 2020-2021

Time Period	2020	2021	% Difference
British Columbia	0.17%	0.20%	**15.5%**
Alberta	0.56%	0.59%	**5.2%**
Saskatchewan	0.04%	0.04%	**-16.7%**
Manitoba	0.18%	0.18%	**1.0%**
Ontario	0.77%	0.84%	**8.1%**
Quebec	0.62%	0.63%	**2.9%**
New Brunswick	0.64%	0.81%	**26.9%**
Nova Scotia	0.64%	0.67%	**5.3%**
Prince Edward Island	0.46%	0.28%	**-39.4%**
Newfoundland	0.48%	0.43%	**-10.1%**
National	0.61%	0.64%	**4.4%**

Cost Concentration

As evident in previous years, a relatively small portion of claimants is responsible for a disproportionately large share of overall expenditures. In 2021, 54.3 per cent of the total adjudicated HBM+ drug cost was associated with the top five per cent of claimants, and 32.3 per cent was associated with the top one per cent of claimants. The cost concentration appears to be intensifying – the share of cost for the top five per cent of HBM+ claimants made up an increasing share of total drug cost over the years, from 50.7 per cent in 2017 to 54.3 per cent in 2021.

In 2021, the top five per cent most expensive claimants cost 21 times more on average, compared to the remaining 95 per cent of the claimant population ($10,538 versus $466). These high-cost claimants had six times more claims (77 claims versus 11) at an average cost per claim that was more than double that of the rest of the claimant population ($137 versus $43).

TABLE 2.3 | Total drug cost distribution by claimant group, 2021

Claimant Group	2017 Share of Total Drug Cost	2021 Share of Total Drug Cost	2021 Average Claims per Claimant	2021 Average Cost per Claim	2021 Average Annual Cost per Claimant
Top 1%	29.4%	32.3%	75	$420	$31,327
Top 5% (Includes Top 1%)	50.7%	54.3%	77	$137	$10,538
All other 95%	49.3%	45.7%	11	$43	$466

The high-cost claimants not only made up most of the total drug cost, but a large percentage of them also stayed high-cost claimants for three or more consecutive years. About 46 per cent of the top five per cent of claimants from 2019 was also ranked in the top five per cent in both 2020 and 2021.

This relatively high persistence of high-cost claimants warrants not only the consideration of strategies to ensure both appropriateness of continued usage of high-cost drugs, but also patient support through strategies such as comprehensive case management provided by specialty pharmacies. Given their expertise in managing complex diseases that require usage of high-cost biologic and other specialty drug products, specialty pharmacies are ideally positioned to play a growing role in these integrated care processes.

TABLE 2.4 | Proportion of high-cost claimants that remain in the same group for three consecutive years

Claimant Group	2017-2019	2018-2020	2019-2021
Top 1%	48.2%	49.0%	47.3%
Top 5% (Includes Top 1%)	46.4%	47.9%	45.8%

The importance of effective high-cost claimant management is underscored by the fact that the most expensive sub-group ($50,001+ per year) is growing the fastest (110 per cent between 2017 and 2021). Indeed, as indicated in Figure 2.3, there is a near-linear relationship between the rate of growth of a particular sub-group of claimants and their annual treatment cost – with more expensive claimants growing faster.

FIGURE 2.3 | Change in the number of claimants by annual treatment cost range, 2017 vs. 2021

Delving a bit deeper into the characteristics of these high-cost claimants, patients suffering from rheumatoid arthritis (RA), Crohn's disease, colitis, and psoriasis represented the largest share of total drug cost in both the top one per cent and top five per cent high-cost claimant groups (Table 2.5). While the claimants in the top one per cent typically required specialty medications to manage their conditions, the top five per cent high-cost claimants, in contrast, suffered from more common chronic diseases, such as diabetes, asthma, anxiety and depression, attention deficit hyperactivity disorder (ADHD), and pain.

Diabetes, in particular, had a different dynamic in the two categories; it represented the second-largest share of drug costs in the top five per cent claimant group, compared to the tenth-largest share in the top one per cent group. This was due to the high prevalence of the disease, paired with an escalating cost of treatment per patient driven by utilization of newer antidiabetic agents.

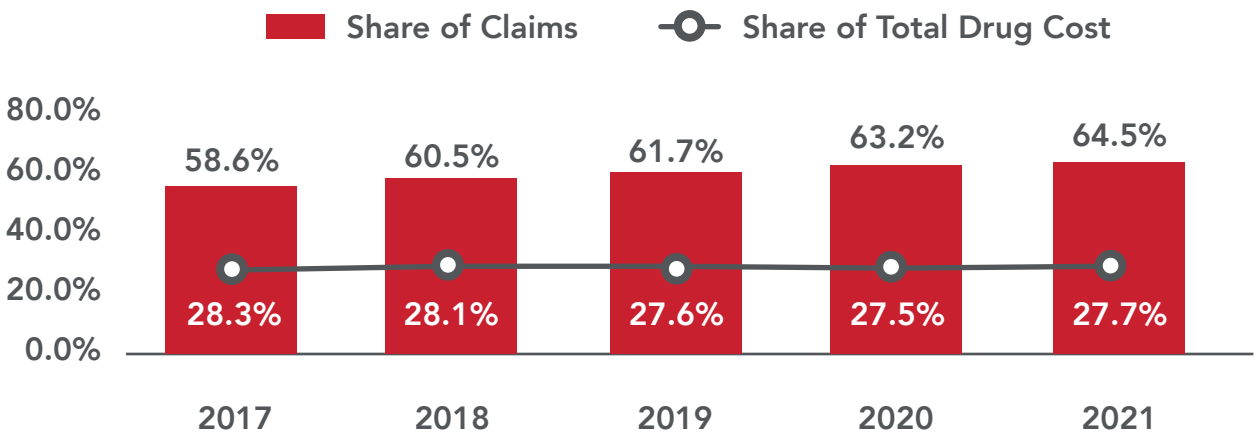
TABLE 2.5 | Top 10 disease states by share of total drug cost for top one per cent and top five per cent of high-cost claimants, 2021

Top 1%			Top 5%		
Rank	Disease State	Share of Total Drug Cost	Rank	Disease State	Share of Total Drug Cost
1	RA/Crohn's/ Colitis/Psoriasis	45.2%	1	RA/Crohn's/Colitis/ Psoriasis	29.7%
2	Cancer	12.7%	2	Diabetes	8.9%
3	Multiple Sclerosis	7.3%	3	Cancer	8.7%
4	Asthma and COPD	3.9%	4	Multiple Sclerosis	5.0%
5	Skin Irritations/ Conditions	2.9%	5	Asthma and COPD	4.1%
6	Cystic Fibrosis	2.9%	6	Anxiety/Depression	2.5%
7	HIV	2.7%	7	HIV	2.2%
8	Macular Degeneration	1.9%	8	Skin Irritations/ Conditions	2.1%
9	Paroxysmal Nocturnal Haemoglobinuria (PNH)	1.8%	9	ADHD	2.0%
10	Diabetes	1.2%	10	Pain	1.8%

Generic Utilization

Increasing the utilization of generic drugs continues to be an important element of cost management in private drug plans, and mandatory generic policies are an essential vehicle to achieving those savings. Generic products continued to make up a greater share of claims within HBM+, accounting for 64.5 per cent of all claims in 2021 up from 63.2 per cent in 2020 (Figure 2.4). While this growth in generic penetration is encouraging, there is room for upwards growth. For reference, public plans in Canada have achieved generic penetration rates of 71 per cent, and in the United States, generic penetration has reached over 80 per cent.*

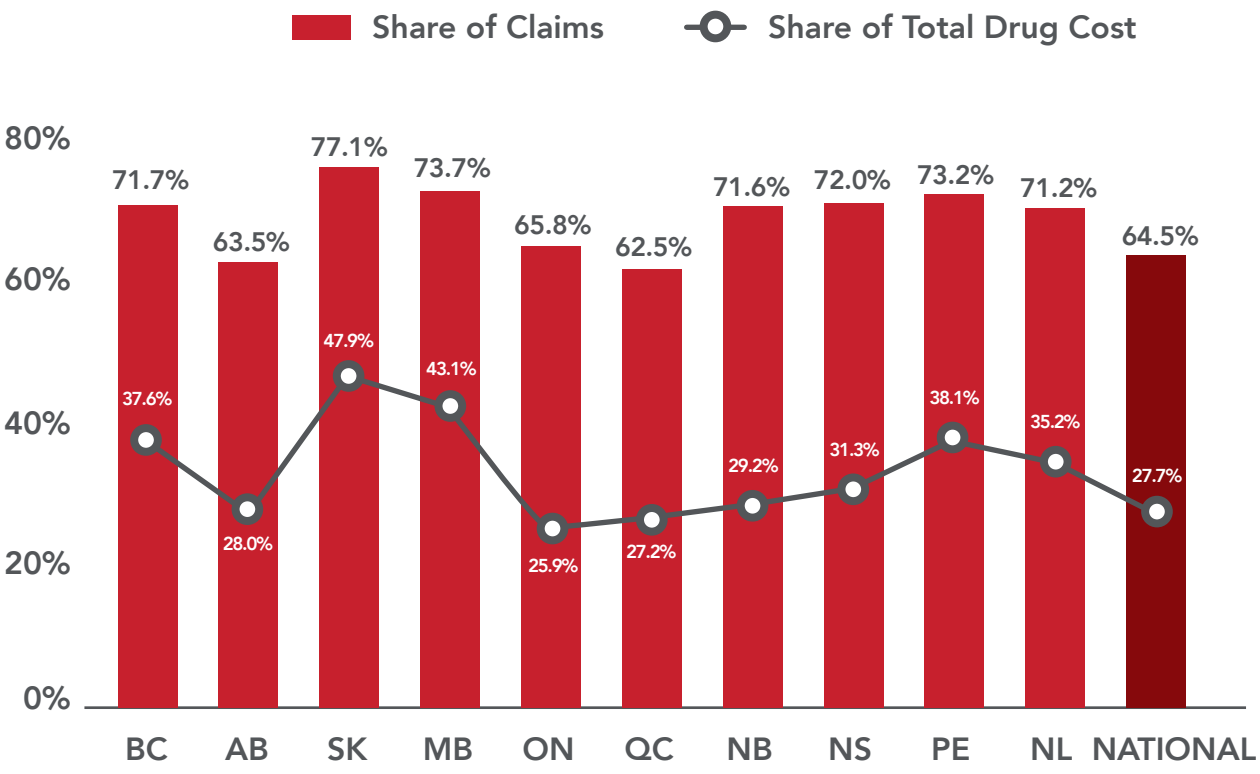
FIGURE 2.4 | Generic share of claims and total drug cost, 2017 to 2021



At the provincial level, the Atlantic provinces had some of the highest generic penetration rates at over 70 per cent, while Ontario and Quebec, the two largest provinces in expenditure, had two of the lowest generic-fill rates at 65.8 per cent and 62.5 per cent, respectively.

* "CompassRx", 7th Edition 2019-2020, and "Generics360" report, 2018 edition; NPDUIS (National Prescription Drug Utilization Information System) Analytical Studies; Patented Medicine Prices Review Board; Government of Canada website; http://www.pmprb-cepmb.gc.ca/en/npduis/analytical-studies

FIGURE 2.5 | Generic share of claims and costs by province, 2021



Top 10 Therapeutic Classes*

Despite only 5.6 per cent of claimants submitting claims for rheumatoid arthritis (RA)/Crohn's/colitis/psoriasis medications in 2021, these inflammatory conditions made up the largest share of total drug cost, accounting for 17 per cent (Table 2.6). Diabetes continues to grow not only in prevalence at 6.7 per cent but also in overall share of costs (7.6 per cent in 2021 compared to 6.6 per cent in 2017).

* Note that the disease states are determined using the primary indication of an individual drug. The prevalence rates are calculated as a share of the total number of HBM+ claimants who claimed drugs associated with a specific disease state.

TABLE 2.6 | Top therapeutic classes by total drug costs, 2017 vs. 2021

Disease State	2021		2017	
	Prevalence Rate	Share of Total Drug Cost	Prevalence Rate	Share of Total Drug Cost
RA/Crohn's/Colitis/Psoriasis	5.6%	17.0%	5.4%	13.7%
Diabetes	6.7%	7.6%	5.6%	6.6%
Anxiety/Depression	22.0%	6.0%	18.6%	6.2%
Cancer	1.7%	5.1%	1.3%	3.9%
Asthma and COPD	12.5%	5.0%	15.4%	5.7%
ADHD	5.8%	5.0%	4.0%	4.1%
Hypertension	18.5%	4.0%	16.6%	5.4%
Acid Related Gastrointestinal Conditions	17.0%	3.1%	14.4%	3.6%
Elevated Cholesterol	13.6%	2.7%	11.7%	3.2%
Multiple Sclerosis	0.1%	2.7%	0.1%	3.0%

TABLE 2.7 | Top therapeutic classes by prevalence rate, 2017 vs. 2021

Disease State	2021		2017	
	Prevalence Rate	Share of Total Drug Cost	Prevalence Rate	Share of Total Drug Cost
Infection	35.2%	2.7%	47.0%	4.4%
Anxiety/Depression	22.0%	6.0%	18.6%	6.2%
Pain	18.5%	2.5%	19.3%	3.6%
Hypertension	18.5%	4.0%	16.6%	5.4%
Acid Related Gastrointestinal Conditions	17.0%	3.1%	14.4%	3.6%
Elevated Cholesterol	13.6%	2.7%	11.7%	3.2%
Skin Irritations/Conditions	13.2%	2.3%	12.9%	1.5%
Osteoarthritis	12.8%	0.7%	12.2%	0.9%
Asthma and COPD	12.5%	5.0%	15.4%	5.7%
Allergies	12.3%	1.7%	13.6%	1.7%

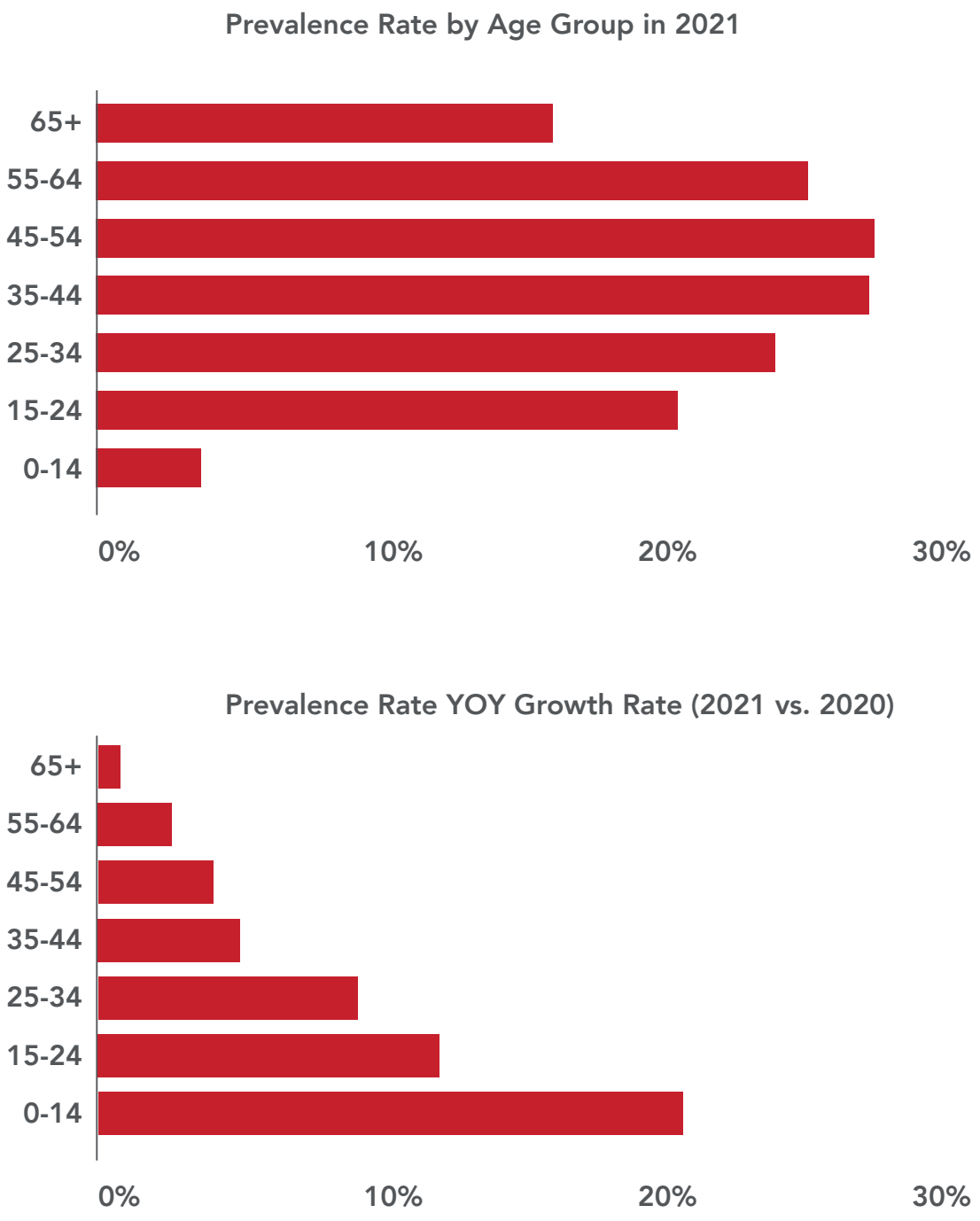
The most prevalent condition continues to be infection, but there was a sizeable drop in the proportion of patients claiming for this condition in 2021 (35.2 per cent) compared to 2017 (47.0 per cent). This is in large part due to measures introduced to manage COVID-19, including ventilation, masking, and disinfection as well as contact restrictions. While most of the measures were widespread in 2020, a number carried over in 2021, including intermittent lockdowns and social distancing.

TABLE 2.8 | Prevalence rates of infection by age group, 2017 to 2021

Age Group	% of Total Claimants Using Infection Medications				
	2017	2018	2019	2020	2021
0-14	65.2%	56.0%	60.1%	50.7%	45.8%
15-24	48.2%	36.4%	43.4%	39.2%	37.7%
25-34	47.5%	46.3%	45.3%	39.8%	37.2%
35-44	48.9%	47.6%	46.1%	40.2%	37.0%
45-54	45.2%	43.8%	42.6%	37.0%	34.1%
55-64	44.4%	43.2%	41.7%	35.7%	33.6%
65+	30.1%	29.8%	28.6%	25.5%	25.1%
Total	**47.0%**	**43.2%**	**43.6%**	**37.8%**	**35.2%**

As the COVID-19 pandemic continued into 2021, its impact was evident on the rates of anxiety and depression. The number of claimants that used medications to manage their anxiety and depression symptoms rose by 7.9 per cent to 463,600 in 2021. This represented 22.0 per cent of all claimants in 2021, up from 20.8 per cent in 2020 and 18.6 per cent in 2017.

FIGURE 2.6 | Anxiety/depression prevalence rates and growth rates by age group, 2021



SECTION 3

Specialty Drugs

Overall Trends

In 2021, there were over 25,000 claimants that used a specialty drug to treat their medical conditions. These specialty drug products were associated with $604 million in total drug costs (Table 3.1). Specialty drug costs grew by 9.0 per cent from 2020 to 2021.

TABLE 3.1 | Specialty drugs total cost, number of claims, and number of claimants, 2017 to 2021

Period	Total Drug Cost		Claims		Claimants	
	Amount	YOY Growth	Number	YOY Growth	Number	YOY Growth
2017	$326.3M	18.2%	115.9K	17.0%	15.5K	19.4%
2018	$349.8M	7.2%	123.6K	6.6%	16.9K	8.8%
2019	$404.3M	15.6%	138.6K	12.1%	19.3K	14.0%
2020	$554.4M	37.1%	184.0K	32.8%	23.3K	20.8%
2021	$604.0M	9.0%	192.5K	4.6%	25.1K	8.0%

Cost and Utilization

The proportion of overall drug spending owing to specialty drugs rose from 28.8 per cent in 2020 to 29.5 per cent in 2021. As in previous years, a very small proportion (1.2 per cent) of claimants was responsible for a large share of overall costs. As evident in Figure 3.1, the contribution of specialty drugs to overall spending has steadily climbed since 2017, and it is not expected to slow down in the near future. The pharmaceutical industry pipeline continues to be dominated by specialty drugs, including biologics and gene therapies.

In a 2021 report by the Patented Medicines Price Review Board (PMPRB), 31 late-stage new medicines were identified based on their potential to significantly impact the Canadian health care system, with some of these medicines potentially offering breakthroughs in treating previously unmet needs or having the potential to treat large patient populations. Additionally, five new medicines are forecasted to reach global revenues over US$1 billion annually by 2027.*

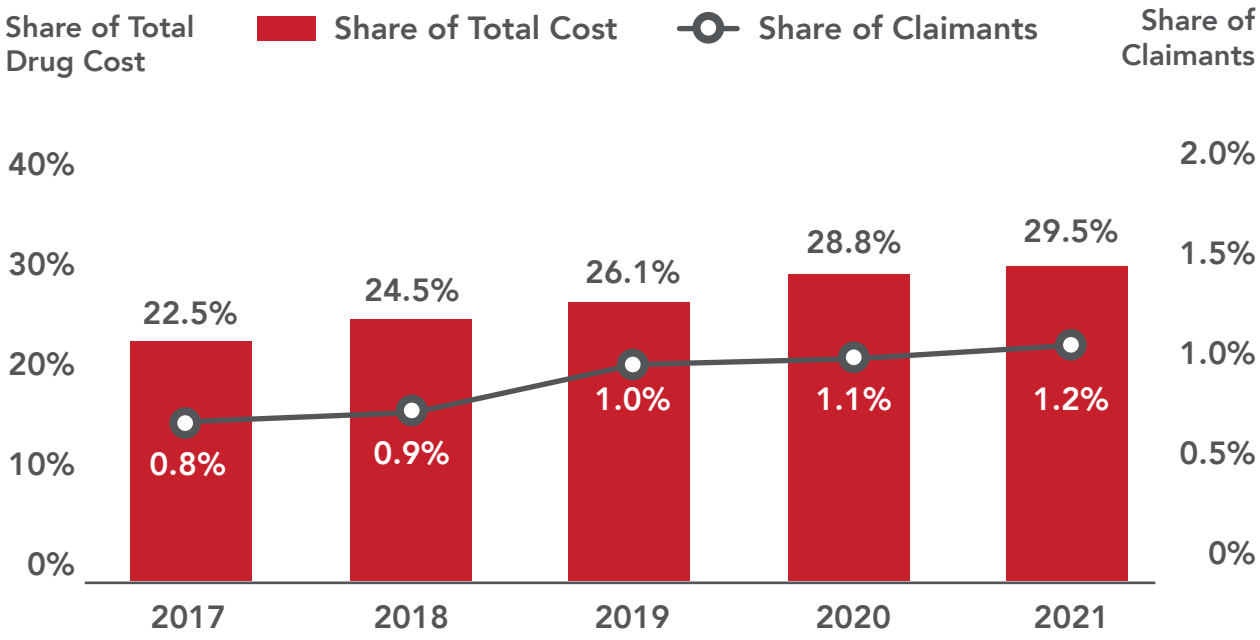
In the United States, specialty drugs reached 49.4 per cent of total prescription drug spending in 2021.** While Canada has not reached this level yet, the current growth rates do put us on a pathway towards it within the next five years. Given these trends, continued vigilance and effective cost and health management strategies are essential in ensuring the sustainability of drug plans – public and private. Furthermore, strategies to manage specialty drug spending will require effective integration across the drug management spectrum from insurance to pharmacy benefits management to pharmacy.

Building on our recent acquisition of NKS Health – a pharmacy specializing in the treatment of complex diseases – HBM+ is ideally positioned to deliver an integrated cost-management platform. By folding NKS Health into our specialty preferred pharmacy network, HBM+ can ensure that effective controls are in place for the management of specialty drugs not only from an initial clinical assessment perspective but also through to optimal patient management leading to improved patient outcomes via the specialty pharmacy.

* "Meds Pipeline Monitor, 2021"; NPDUIS (National Prescription Drug Utilization Information System) Analytical Studies; Patented Medicine Prices Review Board; Government of Canada website; http://www.pmprb-cepmb.gc.ca/en/npduis/analytical-studies.

** Tichy, Eric M., et al. "National Trends in Prescription Drug Expenditures and Projections for 2022. " American Journal of Health-System Pharmacy, 2022, https://doi.org/10.1093/ajhp/zxac102.

FIGURE 3.1 | Specialty drugs share of total drug cost and share of claimants, 2017 to 2021



As noted below (Table 3.2), in 2021, over 25,000 claimants utilized a specialty drug product for the treatment of their condition. The vast majority (more than 95 per cent) of these claimants used products costing between $10,000 and $49,999 per year.

Products costing between $50,000 and $99,999 saw moderate growth in 2021, with products used for oncology treatments, such as Imbruvica and Tagrisso, responsible for 45 per cent of the cost growth within that category. In addition, Radicava (used for amyotrophic lateral sclerosis or ALS) alone made up 28 per cent of product-cost growth for the $50,000–$99,999 category, thanks to its greater claimant utilization, with nearly 30 HBM+ patients using this drug in 2021.

In comparison, specialty products costing from $100,000 to $499,999 saw the largest claimant growth of all specialty product-cost ranges in 2021. The cystic fibrosis medication, Trikafta, was the main contributor of growth, responsible for 62 per cent of the cost growth from the products in the $100,000 to $499,999 range. Nearly 60 new HBM+ claimants used Trikafta in 2021 resulting in $3 million in total drug costs. We will further explore the dynamics of the cystic fibrosis category in Section 5 of this report.

There were four claimants who used specialty products costing more than $500,000. Three of these claimants used Vimizim to treat a genetic disorder, and one claimant used Strensiq for enzyme replacement therapy.

TABLE 3.2 | Number of claimants by cost of specialty products, 2021

Range of Specialty Product Cost	Claimant Measures			Share of Total Drug Cost
	Number of Claimants (2021)	2021 vs. 2020 (Absolute Difference)	YOY Growth (2021)	
$10,000 – $49,999	24.4K	1.8K	7.9%	85.3%
$50,000 – $99,999	0.5K	25	5.3%	6.0%
$100,000 – $499,999	0.3K	65	30.0%	8.3%
$500,000 +	4	-1	-20.0%	0.3%
Grand Total	**25.1K**	**1.8K**	**8.0%**	**100.0%**

The summation of Number of Claimants across different cost ranges could be higher than the Grand Total because some claimants might use more than one specialty product with a different cost range.

The Specialty Product Cost interval is assigned to each specialty product according to its largest annual average drug cost per claimant between 2011 and 2021.

From a disease-state perspective, rheumatoid arthritis (RA)/Crohn's/colitis/psoriasis medications grew by 9.6 per cent and made up about 53 per cent of the specialty products in 2021, reaching just over $321 million in total spending. Cystic fibrosis expenditures, while not in the top five, continued to rise at a fast pace reaching a total of $17 million in 2021, with Trikafta, as mentioned above, contributing $3 million towards that total.

Asthma and chronic obstructive pulmonary disease (COPD) medications made up 4.3 per cent of the total specialty drug costs in 2021. Unlike the double-digit growth rate prior to 2021, the total drug cost for the specialty products used for respiratory conditions, including Xolair and Nucala, declined by 0.6 per cent year over year in 2021 to $25.7 million. The surprising decrease was mainly driven by a 12 per cent decrease in the average number of claims per Xolair claimant and an 8.3 per cent decrease in the average number of claims per Nucala claimant. These two medications made up 65 per cent and 18 per cent, respectively, of total asthma and COPD specialty total drug costs in 2021.

Asthma and chronic obstructive pulmonary disease (COPD) medications made up 4.3 per cent of the total specialty drug costs in 2021.

Specialty medications used to treat skin irritations/conditions represented a growing portion of total specialty drug costs in 2021. Dupixent was the sole specialty medication in this category with substantial year-over-year drug-cost growth, which is mainly attributable to greater utilization.

TABLE 3.3 | Top 10 disease states treated by specialty drugs in 2021 and associated year-over-year cost growth

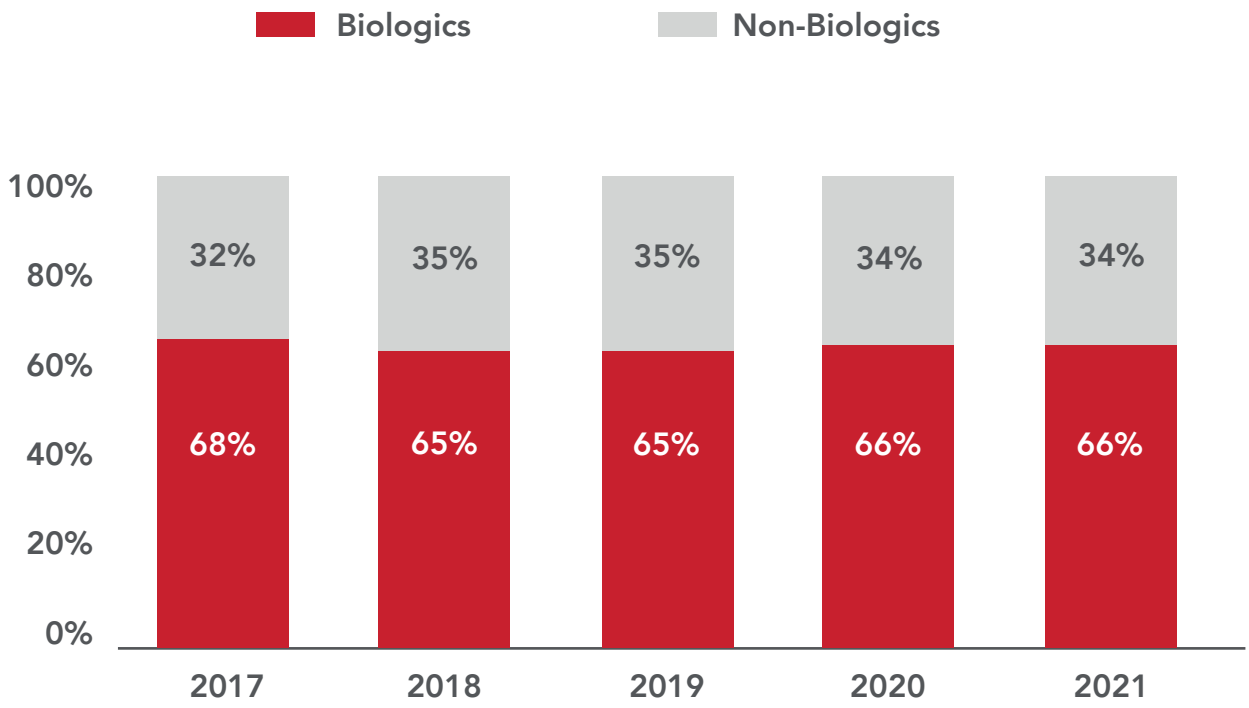
Top 10 Disease States	2017 vs. 2016	2018 vs. 2017	2019 vs. 2018	2020 vs. 2019	2021 vs. 2020
RA/Crohn's/Colitis/ Psoriasis	17.1%	2.9%	14.6%	38.5%	9.6%
Cancer	31.4%	18.5%	5.8%	44.3%	6.1%
Multiple Sclerosis	10.6%	1.1%	8.9%	10.7%	3.6%
Asthma and COPD	21.0%	9.4%	13.3%	40.3%	-0.6%
Skin Irritations/ Conditions	N/A	N/A	141.0%	75.3%	56.0%
Cystic Fibrosis	123.6%	37.8%	44.1%	68.3%	12.2%
HIV	27.3%	3.8%	12.4%	13.5%	-2.7%
Paroxysmal Nocturnal Haemoglobinuria (PNH)	126.8%	39.3%	21.1%	61.7%	-2.1%
X-linked Hypophosphatemia (XLH)	N/A	N/A	N/A	214.3%	16.6%
Kidney Disorder	80.5%	19.4%	50.3%	40.5%	18.5%

N/A: Not available

Focus on Biologics and Biosimilars

Biologic drugs are the main contributors within specialty product expenditures – they made up 66 per cent of the specialty total drug cost in 2021, which includes 2.3 per cent from biosimilars.

FIGURE 3.2 | Biologic and non-biologic share of specialty drug cost by year, 2017 to 2021



Since 2014, more than 29 biosimilar products impacting private drug plans have been approved and marketed in Canada; 17 of these products were approved after 2019 (Table 3.4). Biosimilars present comparable safety and efficacy to their originator products but at a significantly lower cost.

TABLE 3.4 | Approved biosimilars in Canada*

Approval Date	Biosimilar	Originator Reference Product	Condition(s)	Discount (Relative to Originator)
2014	Inflectra	Remicade	RA/Crohn's/Colitis/ Psoriasis	47%
2015	Basaglar	Lantus	Diabetes	25%
2015	Grastofil	Neupogen	Neutropenia	17%
2016	Brenzys	Enbrel	RA/Psoriasis	40%
2017	Admelog	Humalog	Diabetes	25%
2017	Erelzi	Enbrel	RA/Psoriasis	40%
2017	Renflexis	Remicade	RA/Crohn's/Colitis/ Psoriasis	50%
2017	Glatect**	Copaxone**	Multiple Sclerosis	32%
2018	Hadlima	Humira	RA/Crohn's/Colitis/ Psoriasis	40%
2018	Fulphila	Neulasta	Neutropenia	44%
2018	Lapelga	Neulasta	Neutropenia	44%
2019	Truxima	Rituxan	RA/Granulomatosis with Polyangiitis (GPA)/ Microscopic Polyangiitis (MPA)	38%
2020	Avsola	Remicade	RA/Crohn's/Colitis/ Psoriasis	50%
2020	Riximyo	Rituxan	RA/GPA/MPA	38%

(continued onto next page)

* This table reflects biosimilars that are relevant to private plans and were approved as of May 1, 2022.

** Glatect and Copaxone are considered non-biologic complex drugs.

TABLE 3.4 | Approved biosimilars in Canada* (continued)

Approval Date	Biosimilar	Originator Reference Product	Condition(s)	Discount (Relative to Originator)
2020	Ruxience	Rituxan	RA/GPA/MPA	38%
2020	Nivestym	Neupogen	Neutropenia	17%
2020	Ziextenzo	Neulasta	Neutropenia	44%
2020	Nyvepria	Neulasta	Neutropenia	44%
2020	Trurapi	NovoRapid	Diabetes	27%
2020	Amgevita	Humira	RA/Crohn's/Colitis/ Psoriasis	40%
2020	Hulio	Humira	RA/Crohn's/Colitis/ Psoriasis	40%
2020	Hyrimoz	Humira	RA/Crohn's/Colitis/ Psoriasis	40%
2020	Idacio	Humira	RA/Crohn's/Colitis/ Psoriasis	40%
2020	Noromby	Lovenox	Thromboembolic Disorders	20%
2020	Inclunox	Lovenox	Thromboembolic Disorders	20%
2020	Redesca	Lovenox	Thromboembolic Disorders	20%
2021	Riabni	Rituxan	RA/GPA/MPA	38%
2021	Abrilada	Humira	RA/Crohn's/Colitis/ Psoriasis	40%
2022	Simlandi	Humira	RA/Crohn's/Colitis/ Psoriasis	40%

* This table reflects biosimilars that are relevant to private plans and were approved as of May 1, 2022.

Biosimilars continued to gain momentum throughout HBM+ business in 2021. Their total drug cost reached $27.9 million, which represents an increase of 33 per cent from the previous year (Figure 3.3).

> Biosimilars continued to gain momentum throughout HBM+ business in 2021.

This significant growth was led by the biosimilars of Remicade (Inflectra, Renflexis, Avsola, and Remsima). Their combined total drug cost rose by nearly 60 per cent year over year to $9.8 million in 2021 (Figure 3.4). They were responsible for 53 per cent of the biosimilar total drug-cost growth followed by the biosimilars of adalimumab (Humira), which contributed 24 per cent of the overall growth in biosimilar total drug cost.

FIGURE 3.3 | Biosimilar expenditures, 2017 to 2021

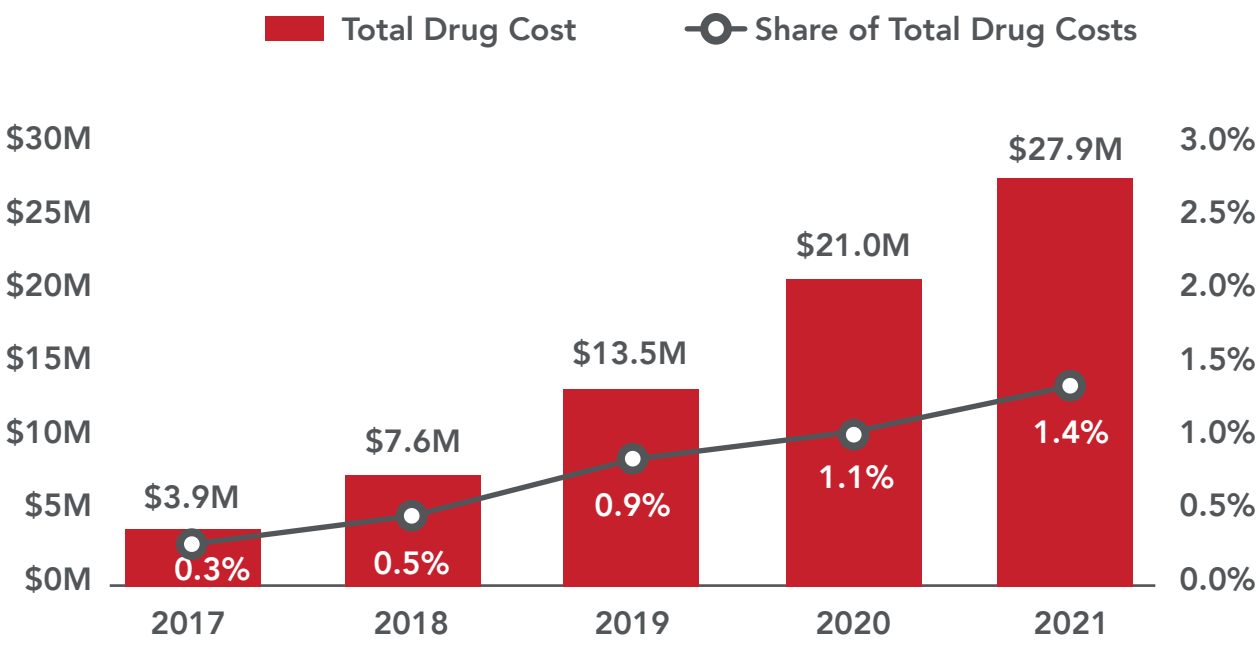
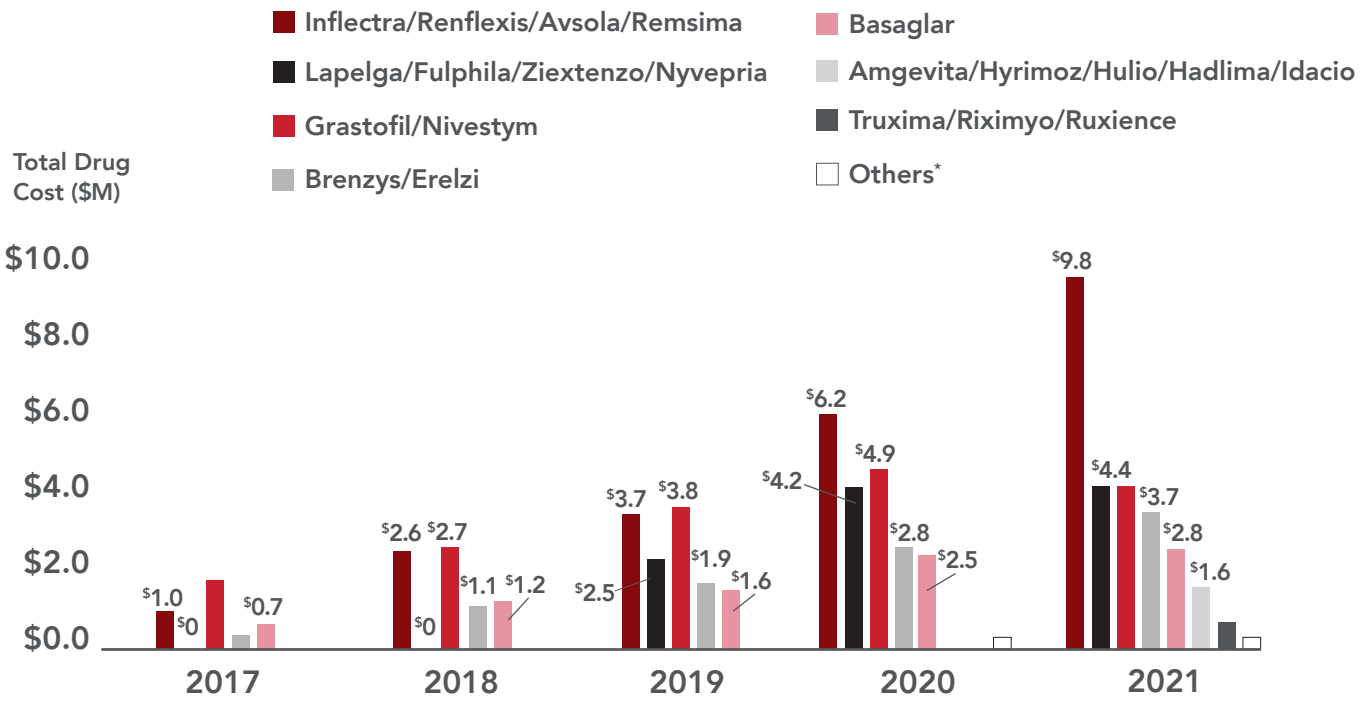


FIGURE 3.4 | Biosimilar total drug costs by drug, 2017 to 2021



* Note: Others include the total drug costs from the biosimilar drugs bevacizumab, insulin lispro, teriparatide, enoxaparin, insulin aspart, and trastuzumab.

TABLE 3.5 | Biosimilars share of claims by molecule, 2021

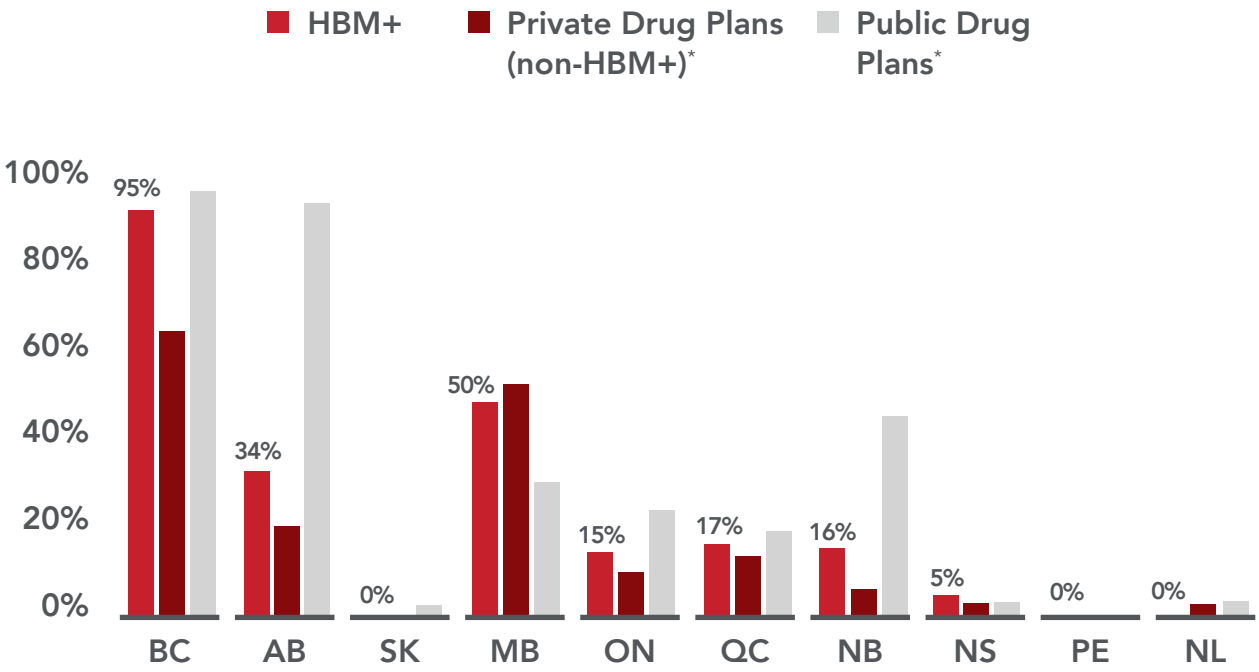
Molecule	HBM+	Other Private Drug Programs*	Ontario Public Drug Program*	RAMQ*
	Biosimilar Share of Claims			
Infliximab (Remicade)	17.2%	12.6%	24.8%	19.9%
Adalimumab (Humira)	3.9%	2.7%	7.2%	6.7%
Etanercept (Enbrel)	35.6%	28.8%	38.8%	32.4%
Insulin Lispro (Humalog)	4.4%	0.8%	2.8%	9.6%
Insulin Glargine (Lantus)	51.8%	26.6%	2.7%	42.2%

* Source: IQVIA, PharmaStat

We are pleased to see provincial government policies that implement biosimilar transitioning under their health care plans have now been launched in British Columbia, Alberta, New Brunswick, Quebec, Northwest Territories, and Nova Scotia. These policies have had the effect of driving biosimilar adoption in each of these provinces, but due to the timing of implementation, there are dramatic differences in biosimilar penetration across the country, with a strong west-to-east gradient.

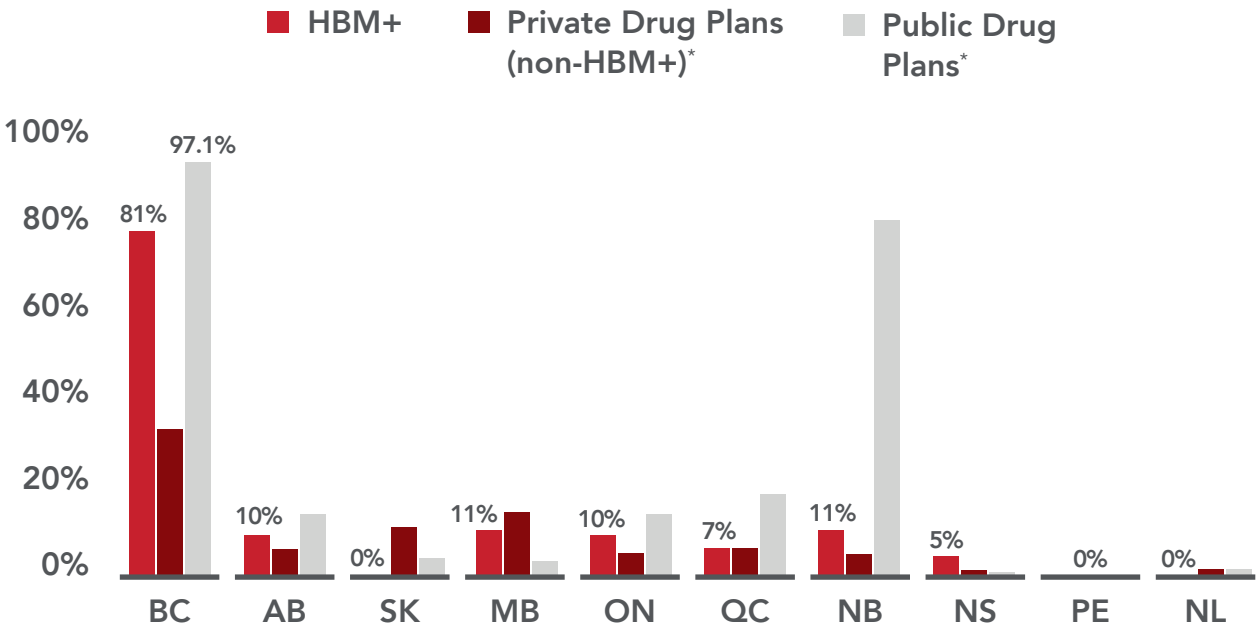
For example, biosimilars of Remicade (infliximab) had the highest HBM+ market share in British Columbia at 95 per cent in 2021, with 17 per cent and 15 per cent penetration in Quebec and Ontario, respectively. Humira biosimilars showed a strong increase in penetration since Q2 2021, especially in British Columbia. In the fourth quarter of 2021, Humira biosimilars made up 81 per cent of HBM+ adalimumab claims (Figure 3.6).

FIGURE 3.5 | Biosimilar penetration of infliximab by province, 2021



* Source: IQVIA, PharmaStat

FIGURE 3.6 | Biosimilar penetration of adalimumab by province, 2021



* Source: IQVIA, PharmaStat

SECTION 4

Non-Specialty Drugs

Overall Trends

While specialty drugs continue to dominate industry conversations and planning efforts within private plans, there are important trends pertaining to non-specialty drugs starting to emerge, and which require close attention. The dynamics of non-specialty drugs are best illustrated by dividing claimants into cost intervals (Table 4.1). Each of these cost intervals is dominated by specific therapeutic categories such as hyperlipidemia, migraines, and diabetes. The overarching theme is the growing utilization of biologic drugs to treat these relatively common conditions (that have typically been treated with traditional small molecule drugs). This utilization is driving unprecedented growth in spending and will require closer management of not only the appropriateness of drug therapy but also overall disease management. The two fastest growing claimant-cost-interval categories in 2021 were the $1,000–$1,999 and the $5,000–$9,999 intervals; the dynamics of each are outlined below.

TABLE 4.1 | Utilization by claimant cost intervals, 2021

Claimant Cost Interval	Total Drug Cost Growth 2021 vs. 2020	Claimant Growth 2021 vs. 2020
<$500	2.6%	1.8%
$500 – $999	6.3%	4.7%
$1,000–$1,999	**18.8%**	**14.6%**
$2,000 – $2,999	6.6%	4.9%
$3,000 – $3,999	1.6%	1.4%
$4,000 – $4,999	-2.4%	0.4%
$5,000–$9,999	**16.5%**	**17.1%**
Non-Specialty	**5.1%**	**2.0%**
Specialty	**9.0%**	**8.0%**

Claimant Cost Interval $5,000–$9,999

Total costs for claimants in the **$5,000–$9,999** cost interval grew by 16.5 per cent in 2021 rising to a total of $54 million. This exceptional growth was mainly caused by greater utilization of biologic treatments for the top five disease states within this group of medications, including macular degeneration, migraines, high cholesterol, cancer, and HIV. Given the rapidly growing utilization of products in this cost interval, ensuring the appropriate utilization of biologics is going to become increasingly important for effective overall drug-plan cost management. Traditional tools, such as prior authorization, continue to be an essential element of drug plan management for this cost interval, but equally important are disease-based case management approaches. In a case management framework, claimants with specific chronic diseases, such as high cholesterol and diabetes, work with a case manager one-to-one to manage all aspects of their disease, including medication adherence, diet, and exercise among others. Case management, delivered through the combination of technology and human guidance, can be a powerful tool for enabling effective disease control as well as long-term cost management.

TABLE 4.2 | Top five disease states for claimants in the $5,000–$9,999 cost interval, 2021

Rank	Disease State	Share of Total Drug Cost	Total Drug Cost Growth 2021 vs. 2020	Claimant Growth 2021 vs. 2020
1	Macular Degeneration	32.5%	18.9%	6.5%
2	Migraines	15.8%	53.3%	40.8%
3	Elevated Cholesterol	12.8%	16.5%	17.1%
4	Cancer	12.7%	4.5%	13.9%
5	HIV	7.8%	23.8%	31.2%

Macular Degeneration

Total drug cost for eye diseases such as macular degeneration reached $17.6 million in 2021, with Eylea and Lucentis as the only medications in this class. Lucentis made up 32 per cent of the total drug cost, but it was responsible for 40 per cent of the cost growth thanks to its 26 per cent increase in average cost per claimant in 2021. Of note, Byooviz, the first biosimilar for Lucentis was approved by Health Canada in March 2022, promising to offer savings to plan sponsors when it is eventually marketed.

Migraines

Total migraine drug cost jumped by 53 per cent year over year thanks to a more than 40 per cent increase in claimants taking the newer biologic treatments Aimovig, Ajovy, and Emgality. Moreover, this substantial utilization growth also means migraine medications contributed 38.7 per cent of the total drug-cost growth within the cost interval of $5,000–$9,999 products relative to its 15.8 per cent share of total drug cost.

Elevated Cholesterol

Total drug cost for elevated cholesterol medications grew by 16.5 per cent year over year due to an increase in Praluent and Repatha. This noticeable growth was mainly thanks to greater claimant utilization, which had reached 1,300 in 2021 – up by 17 per cent from the previous year.

HIV

This class of medications made up only 7.8 per cent of total drug cost in 2021 down from 31.2 per cent in 2017, thanks to the lower utilization of Truvada, Viread, Isentress, and Prezista which faced strong generic competition. Nevertheless, the number of HIV claimants within the cost interval of $5,000–$9,999 products jumped by 31.2 per cent year over year.

Claimant Cost Interval $1,000–$1,999

Total costs for claimants in the $1,000–$1,999 cost interval grew by 19.0 per cent over the past five years due to consistent double-digit claimant growth. Diabetes is the significant cost driver within this interval, accounting for 57 per cent of the total drug-cost growth in 2021. This increase can be attributed to the greater expenditures for Ozempic, which rose by 67 per cent year over year.

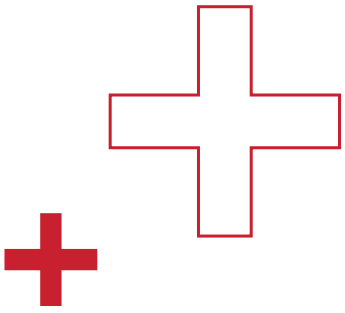
Weight control and medical devices/equipment were other stand-out categories within this product/cost group. Weight control products Contrave and Saxenda made up 18 per cent and 82 per cent of the total drug cost, respectively, within the $1,000–$1,999 cost interval in 2021. They experienced a 41 per cent and 34 per cent year-over-year total drug-cost growth, respectively. This category is expected to grow even further with the arrival of a new, more effective weight control agent called Wegovy in late 2022.

The total drug cost for medical devices/equipment within the $1,000– $1,999 cost interval rose more than 30-fold over the past five years, including a 43 per cent increase in 2021.

The total drug cost for medical devices/equipment within the $1,000–$1,999 cost interval rose more than 30-fold over the past five years, including a 43 per cent increase in 2021. Such significant growth was fully attributed to the greater utilization of glucose monitoring systems, such as Freestyle Libre and Dexcom. These new devices have shown promise in helping insulin-dependent diabetic patients better manage their blood glucose through more real-time monitoring and insights.

TABLE 4.3 | Top five disease states for claimants in the $1,000–$1,999 cost interval, 2021

Rank	Disease State	Share of Total Drug Cost	Total Drug Cost Growth 2021 vs. 2020	Claimant Growth 2021 vs. 2020
1	Diabetes	31.5%	40.1%	43.2%
2	Weight Control	11.6%	36.0%	33.1%
3	ADHD	9.0%	9.8%	8.2%
4	Cervical Dystonia	7.0%	16.1%	11.5%
5	Medical Devices/ Equipment	7.0%	43.2%	38.9%



SECTION 5

Emerging & Future Trends

We continuously monitor emerging trends in the drug landscape to prepare and adapt our programs and services to meet our partners' needs. After a thorough review of our claims data and literature, we have identified four areas – digital pharmacy, diabetes, obesity, and cystic fibrosis – that are likely to have a high impact on private benefit plans in 2022. We close this section by looking further into the future and identifying the pipeline of new drugs likely to impact plans in subsequent years.

Digital Pharmacy

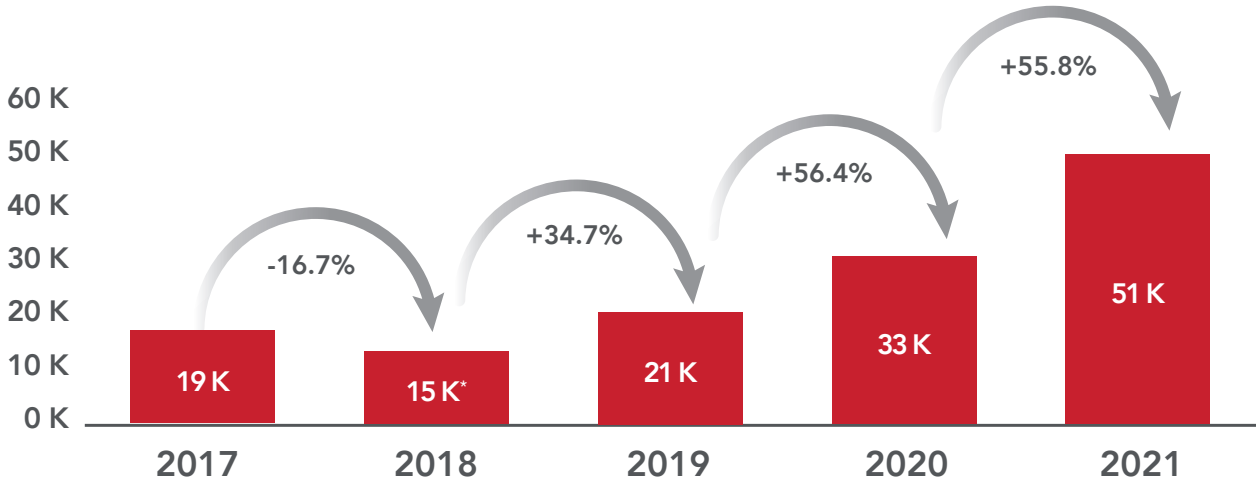
The global COVID-19 pandemic has dramatically shifted Canadians' utilization of various health care services. Lockdowns and distancing requirements have resulted in more Canadians turning to virtual options to obtain their care. As the pandemic has carried into a third year, many of these health care consumption behaviours appear to be here to stay, namely those pertaining to digital services.

Pharmacy has absolutely been affected by this movement, as digital pharmacy has provided patients with new ways of interacting with their pharmacy providers. Even in advance of COVID-19, several new digital pharmacy startups entered the Canadian marketplace, including PocketPills, Pillway, Mednow, Health Depot, and others. Digital pharmacies rely on the same model of drug distribution as "mail-order" pharmacies, but they elevate the patient experience to a much higher level, including connections through web and mobile applications combined with home delivery of medications.

Throughout the pandemic, Canadians have increasingly relied on online shopping and home delivery for obtaining a wide array of products. We expect that these online behaviours will continue to translate into further adoption of digital pharmacy as a means of obtaining medications. This is particularly true for chronic diseases where medications are taken on an ongoing basis, and automatic refills can be easily enabled via home delivery.

HBM+ data trends support these assertions – the number of claims for non-specialty medications obtained through digital pharmacies grew 55.8 per cent in 2021 compared to 2020 (Figure 5.1). Specifically, there were nearly 51,000 non-specialty prescriptions delivered by digital pharmacies in 2021. This represents 0.17 per cent of non-specialty product claims in 2021, up from 0.11 per cent in 2020.

FIGURE 5.1 | Number of claims and annual growth rate for digital pharmacies, 2017 to 2021



* The decline in digital pharmacy claims in 2018 is attributable to the implementation of OHIP+ program.

Delving a bit deeper into the dynamics of the traditional versus digital pharmacy models reveals some interesting trends:

- First, digital pharmacies charge lower dispensing fees than their traditional counterparts – on average under $8 per prescription compared to $9–$11 for traditional pharmacies (Table 5.1).
- Second, digital pharmacies tend to dispense larger quantities (days' supply) of medications compared to traditional pharmacies – on average 54 days per claim compared to 36–51 days for traditional pharmacies (Table 5.2).

For both of these reasons – lower dispensing fees and higher quantity supplied – digital pharmacies have garnered growing interest and adoption from Canadian plan sponsors and HBM+ partners, offering the opportunity to provide their plan members with a convenient pharmacy option while saving plan dollars.

TABLE 5.1 | Average dispensing fees by pharmacy type and province, 2021

Average Dispensing Fee per Claim				
Province	Chain Banners	Food Stores	Independent	Digital Pharmacy
BC	$10.43	$8.52	$10.11	$7.87
AB	$11.99	$10.55	$11.87	$8.62
SK	$11.65	$10.82	$11.74	$7.50
MB	$11.86	$9.90	$12.14	$7.56
ON	$11.51	$8.80	$10.95	$8.05
NB	$11.55	$8.53	$11.84	$7.04
NS	$12.13	$9.68	$11.93	$7.66
PE	$12.20	$11.55	$12.32	Not Available
NL	$11.42	$7.76	$11.67	$7.17
National*	$11.38	$9.09	$10.92	$8.00

* Excluding Quebec. In Quebec, professional fees apply in place of dispensing fees and pharmacy markups.

TABLE 5.2 | Average quantities dispensed by pharmacy type and province, 2021

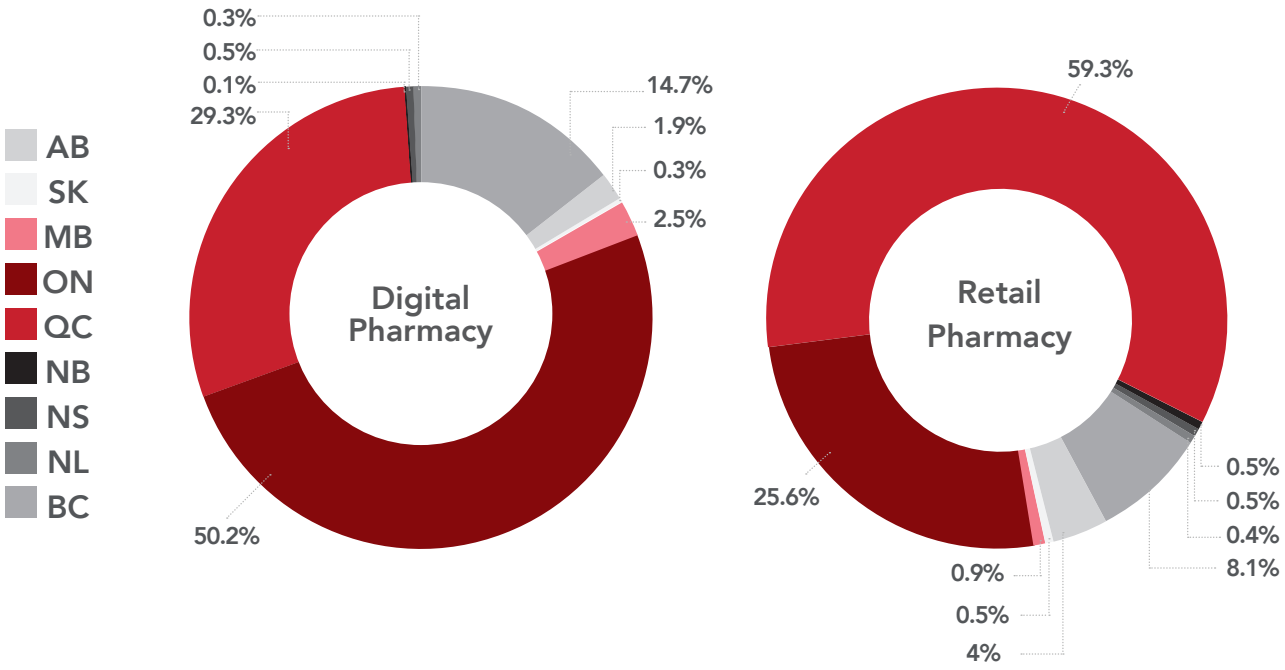
Average Days' Supply per Claim				
Province	Chain Banners	Food Stores	Independent	Digital Pharmacy
BC	46.7	55.3	42.5	61.8
AB	41.1	47.9	34.2	55.3
SK	35.4	38.7	34.9	61.5
MB	42.8	49.8	39.1	53.0
ON	39.2	49.5	35.0	51.0
NB	45.4	53.4	56.8	57.2
NS	47.8	53.0	44.2	58.4
PE	47.0	47.7	45.2	Not Available
NL	45.6	50.6	42.8	48.8
National*	41.0	51.0	36.0	53.5

*Excluding Quebec

Looking at the provincial dynamics (Figure 5.2 below), digital pharmacy claims were concentrated largely in the provinces of Ontario (50.2 per cent), Quebec (29.3 per cent), and British Columbia (14.7 per cent). Retail pharmacy claims were also primarily concentrated in the same three provinces, but Quebec led the way with 59.3 per cent of the overall share.

From a growth perspective, digital pharmacy claims increased in most provinces (except New Brunswick) in 2021, with the most prominent growth in Ontario (41 per cent) and Quebec (37 per cent).

FIGURE 5.2 | Claims distribution by pharmacy type and province, 2021



Maintenance medications for chronic disease are an ideal category for distribution through digital pharmacies given the predictable nature of dispensing, compared to medications used to treat acute conditions which are often required on short notice.

The prevalence of chronic disease in the digital pharmacy claimant population is also evident in the distribution of the top disease states (Table 5.3). All the top 10 disease states are typically chronic in nature with anxiety and depression plus hypertension leading the way.

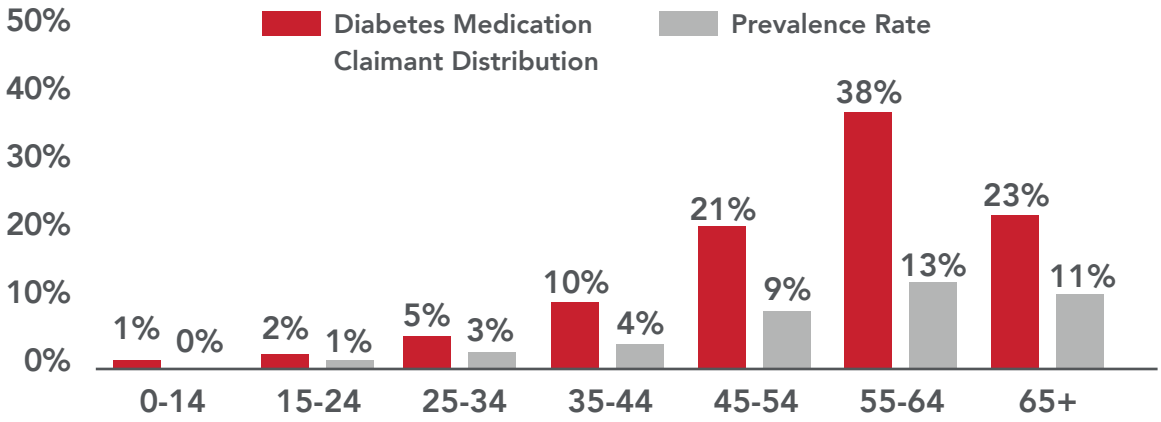
TABLE 5.3 | Top 10 diseases among patients utilizing digital pharmacy channels, 2021

Disease State	Share of Claims	Share of Total Drug Costs
Anxiety/Depression	13.4%	9.6%
Hypertension	10.8%	4.6%
Birth Control	10.1%	7.6%
Diabetes	7.1%	16.5%
Elevated Cholesterol	6.1%	2.8%
Skin Irritations/Conditions	5.7%	4.3%
Acid Related Gastrointestinal Conditions	4.7%	4.3%
Asthma and COPD	3.8%	5.8%
Allergies	3.4%	3.0%
Thyroid Condition	3.2%	0.9%
Top 10 Total	**68.4%**	**59.5%**

Diabetes

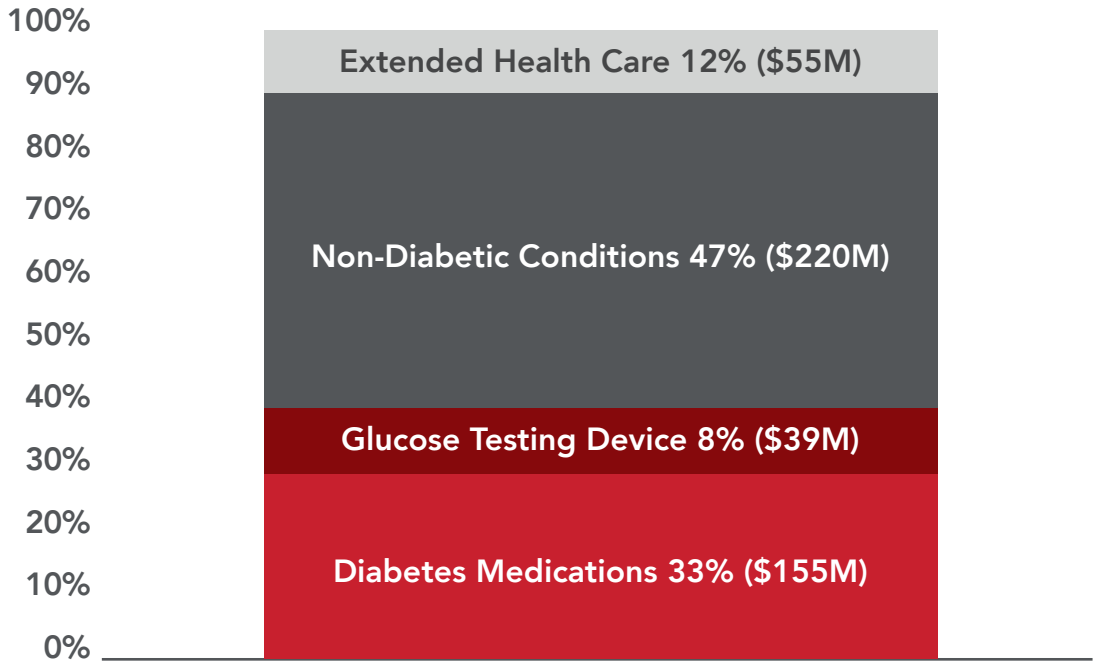
The number of HBM+ claimants taking diabetes medications has been rising for years: an estimated 141,000 were using at least one diabetes medication in 2021, up 32 per cent from 2017. The diabetes prevalence rate also increased to 6.7 per cent of HBM+ claimants in 2021, up from 5.6 per cent in 2017. In general, the diabetes prevalence rate rose in conjunction with age (Figure 5.3), with the majority of diabetic patients being over the age of 55. The dip in prevalence in the 65+ age group is due to the effects of provincial coordination with plan members typically having the majority of their diabetic claims processed through provincial drug plans.

FIGURE 5.3 | Diabetes medication claimants distribution and prevalence rate by age group, 2021



Overall health expenditures for claimants with diabetes reached $469 million in 2021 with an average claimant cost of approximately $3,321. Diabetes medications used to manage blood sugar level made up 33 per cent (or $155 million) of the total cost while testing devices to monitor glucose levels made up another eight per cent (or $39 million). An additional 47 per cent (or $220 million) of the expenses for this cohort were for medications for the treatment of non-diabetic conditions. Finally, extended health care services accounted for 12 per cent (or $55 million) of total expenditures (Figure 5.4).

FIGURE 5.4 | Diabetes medication claimant health benefit expenditure, 2021

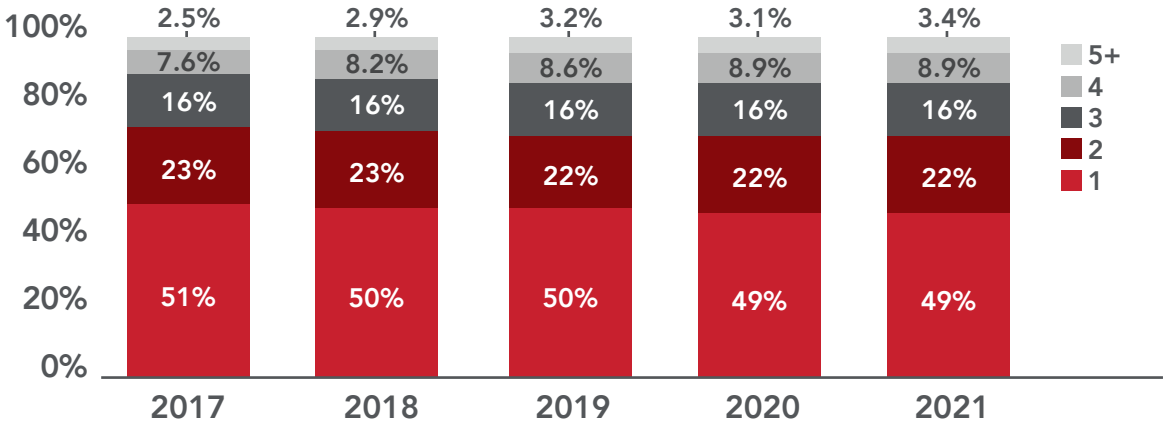


Diabetes Medications

Total spending on diabetes medications used to help manage blood sugar levels rose to $155 million in 2021, up 63 per cent compared to 2017. This was driven by a 32 per cent growth in the number of diabetes medication claimants as well as an increase in the average cost per diabetes claimant. The annual average diabetes medication cost per claimant rose by 23 per cent over the past five years to $1,102 in 2021. This, in turn, was partly driven by a greater number of claimants using multiple classes of diabetic therapy to manage their condition.

Claimants using four or more different diabetic classes within the year made up 12.3 per cent of the total diabetes medication claimant population in 2021, up from 10.1 per cent and 12 per cent in 2017 and 2020, respectively (Figure 5.5). Conversely, the number of diabetes medication claimants using only one class during the year dropped from 51 per cent in 2017 to 49 per cent in 2021.

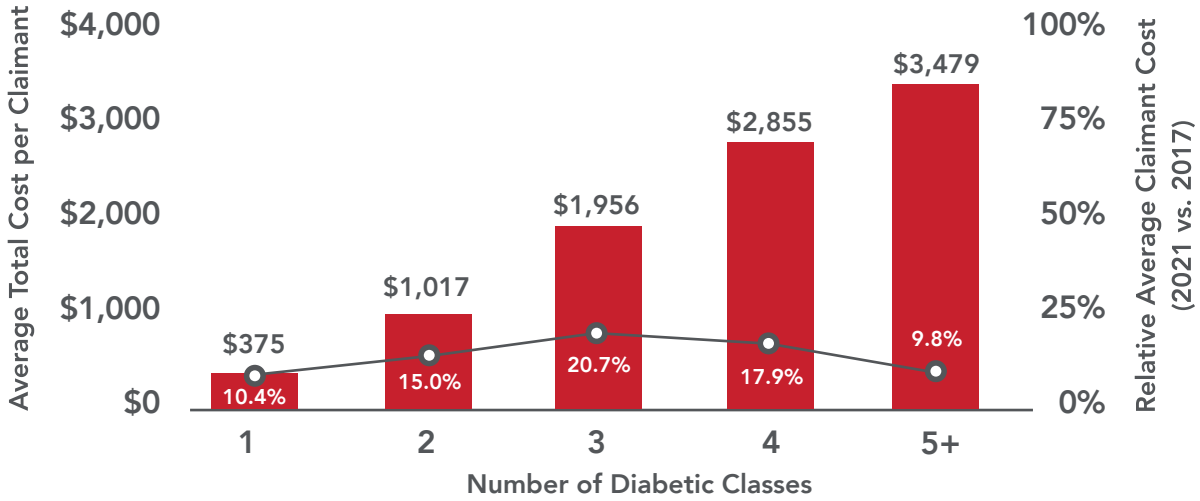
FIGURE 5.5 | Claimant distribution by the number of diabetic classes by year, 2017 to 2021



Note: Diabetic classes include metformin, DPP4 inhibitors, SGLT-2 inhibitors, GLP-1 receptor agonists, thiazolidinediones, alpha-glucosidase inhibitors, sulfonylurea (SU), meglitinides, and insulin.

The greater portion of claimants using four or more classes of diabetes medications in conjunction with a smaller portion using only one class had a substantial impact on overall costs. The average cost for claimants with four or five plus classes was 6.6 times and 8.3 times greater, respectively, than the average cost of claimants using only one class of therapy in 2021 (Figure 5.6).

FIGURE 5.6 | Average total cost per claimant by the number of diabetic classes, 2021



While the mainstay of treatment for diabetes remains metformin, there are a variety of new medication classes that have been introduced in the market over the past 10 years. In particular, the SGLT-2 inhibitors and GLP-1 receptor agonists medication classes have risen dramatically in utilization; 30 per cent and 16 per cent of diabetes medication claimants used SGLT-2 and GLP-1 medications, respectively, in 2021. This represents an increase of 60 per cent and 147 per cent, respectively, compared to 2017 (Figure 5.7). More importantly, the average claimant cost for these medication classes was eight times and 19 times greater than the average metformin claimant cost (Table 5.8).

FIGURE 5.7 | Share of diabetes medication claimants by diabetic class, 2017 vs. 2021

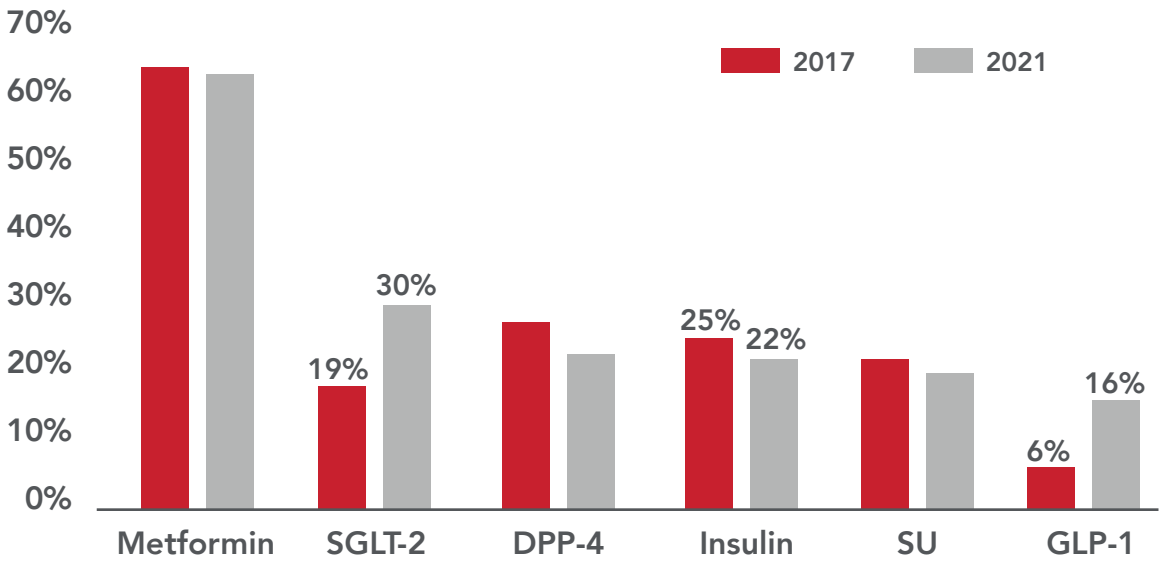
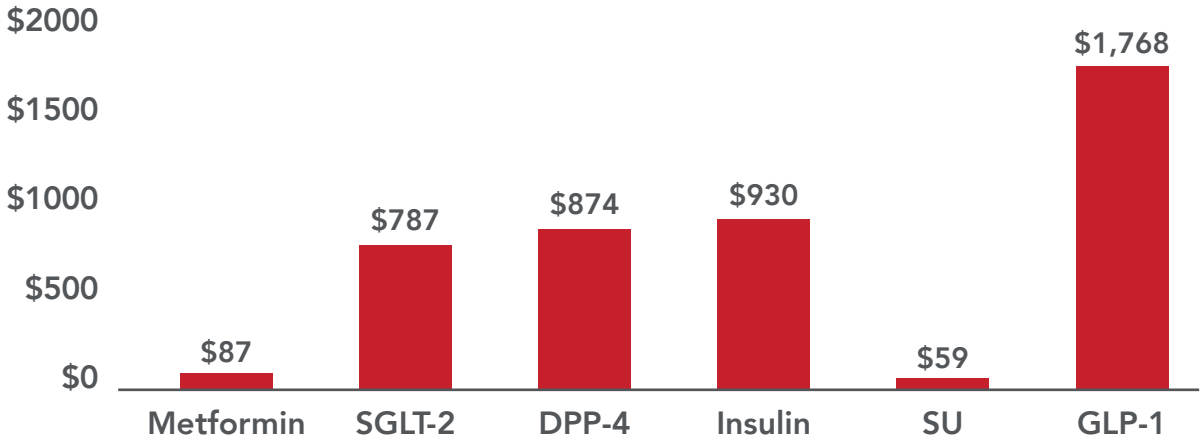


FIGURE 5.8 | Average drug cost per claimant by diabetic class, 2021



Glucose Testing Devices

Glucose testing devices are an important element of the overall management of diabetes. Traditionally, patients have relied on test strips to monitor blood glucose. More recently, highly convenient continuous glucose monitoring (CGM) and flash glucose monitoring (FGM) devices have been introduced on the market.

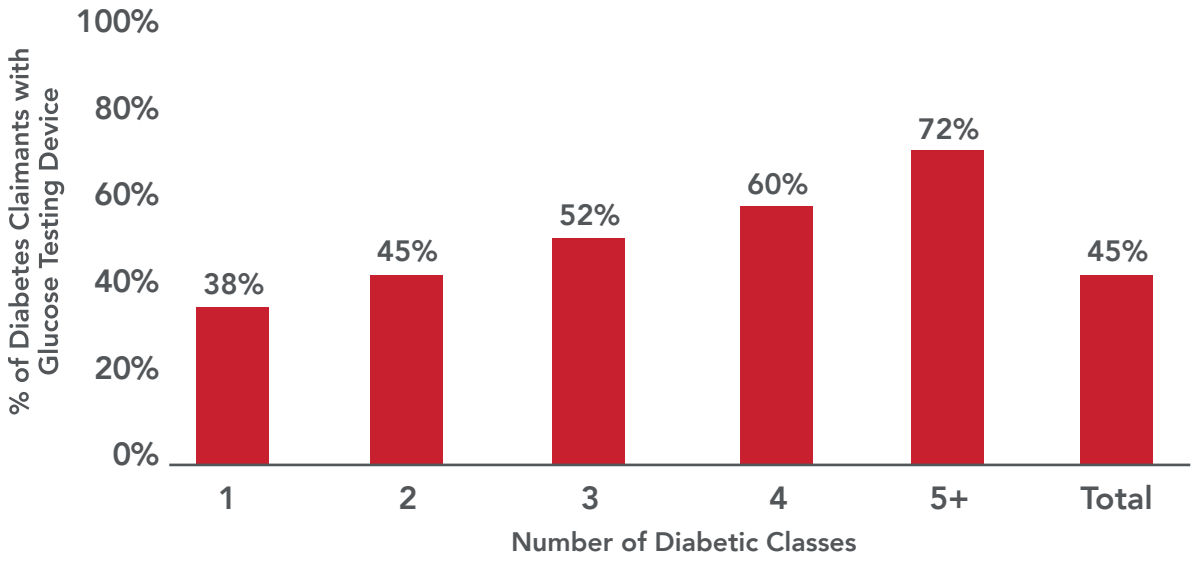
+ **Flash glucose monitoring (FGM)** measures the glucose concentration in the interstitial fluid (the fluid that fills the spaces between cells), and since it is factory calibrated, it does not require capillary blood glucose (with a self-monitoring blood glucose device) calibration.* Even though the blood glucose levels are not continually displayed on the monitoring device, they are displayed when the sensor is "flashed" with a reader device on demand. More importantly, the sensor can be used continuously for up to 14 days.

+ **Continuous glucose monitoring (CGM)** is another new type of device to monitor glucose levels. Unlike the FGM that displays a "flashed" reading, the CGM provides continuous absolute glucose levels, and trending, along with notifications if the glucose level remains outside a pre-set limit.

* Lori D. B, Rick S, Vincent W. Diabetes Canada 2018 Clinical Practice Guidelines for Monitoring Glycemic Control. Can J Diabetes 42 (2018) S47–S53.

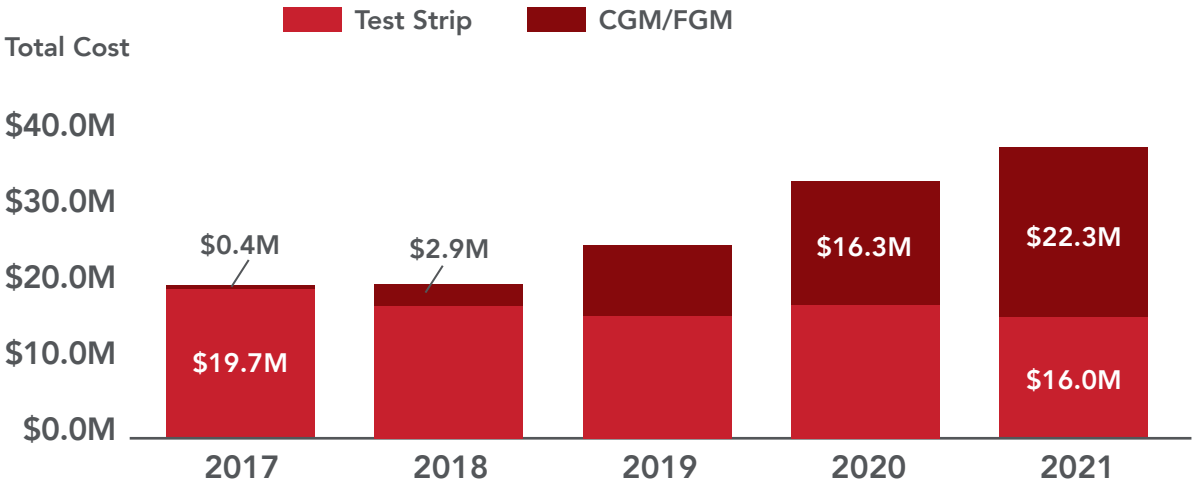
Approximately 45 per cent of diabetes medication claimants (63,000 of the 141,000 total diabetes claimants) used glucose testing devices to monitor their blood sugar level in 2021. There was a direct relationship between the number of medication classes and the proportion of claimants utilizing glucose testing devices. Claimants using five or more different classes of diabetes medications were twice as likely to use testing devices than claimants using only one diabetic class of medication (72 per cent versus 38 per cent).

FIGURE 5.9 | Glucose testing device utilization rate within diabetes medication claimants by number of diabetic classes, 2021



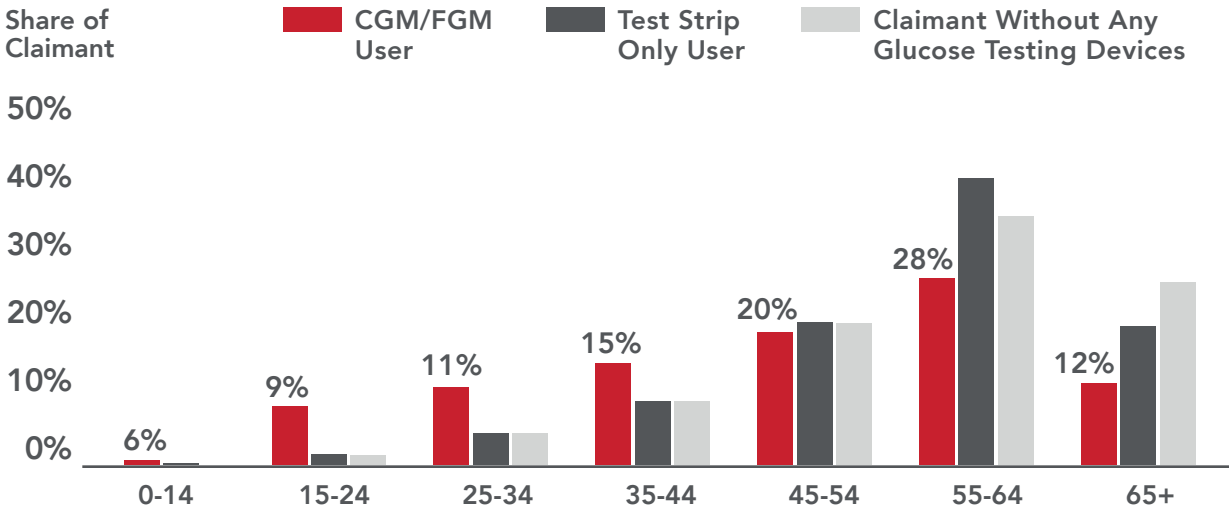
Total spending on glucose testing devices reached $38 million in 2021 which represented a 90 per cent growth over 2017 (Figure 5.10). The relatively large growth in glucose testing spending was due to the introduction of higher-cost CGM/FGM devices in recent years. The average claimant cost of CGM/FGM devices reached nearly $2,000 in 2021, which was more than six times the average test-strip claimant cost. As a result, CGM/FGM devices accounted for 58 per cent of the total glucose testing device spending, even though these devices were only used by 15 per cent of the glucose testing device claimants.

FIGURE 5.10 | Test strip and CGM/FGM total cost, 2021



Younger claimants made up a significant portion of the CGM/FGM diabetes claimants – about 40 per cent of the CGM/FGM claimants were less than 45 years old, which was significantly higher than the other two cohorts where only 16 per cent of claimants were less than 45 years old (Figure 5.11).

FIGURE 5.11 | Diabetic claimants glucose testing mechanism by age group, 2021



Non-Diabetic Conditions

Diabetic patients typically suffer from additional comorbidities. In particular, 47 per cent of diabetic claimants' total health expenditures were for medications to treat non-diabetic conditions. On average, each claimant spent $1,558 on non-diabetic medications in 2021, which was 86 per cent higher than the non-diabetes claimant cohort (Table 5.4). This greater level of spending occurred across each of the top 10 disease states, including eye conditions, elevated cholesterol, and hypertension. Diabetic claimants' larger spending on eye condition medications in particular was likely the result of uncontrolled blood sugar causing complications.

TABLE 5.4 | Top disease states in contribution to the average claimant cost between diabetic and non-diabetic claimants, 2021

	Diabetic Claimants	Non-Diabetic Claimants	
Number of Claimants	**141,000**	**1,969,000**	
Disease State	**Contribution to the Average Claimant Cost**		**Relative Difference**
Rheumatoid Arthritis (RA)/Crohn's/Colitis/ Psoriasis	$194	$162	20%
Hypertension	$153	$31	396%
Elevated Cholesterol	$119	$20	502%
Cancer	$88	$46	89%
Anxiety/Depression	$84	$56	49%
Asthma and Chronic Obstructive Pulmonary Disease (COPD)	$73	$47	54%
Eye Conditions	$70	$4	1,699%
Acid Related Gastrointestinal Conditions	$61	$28	121%
Pain	$56	$22	157%
Blood Clot	$46	$14	225%
Average Cost per Claimant	**$1,558**	**$836**	**86%**

There is a direct relationship between the number of diabetic medication classes used by diabetic patients and the prevalence of various comorbidities (Table 5.5). For instance, over 87 per cent of diabetes claimants utilizing five or more diabetic medication classes had elevated cholesterol compared to only 48 per cent of diabetes claimants utilizing one diabetic medication class.

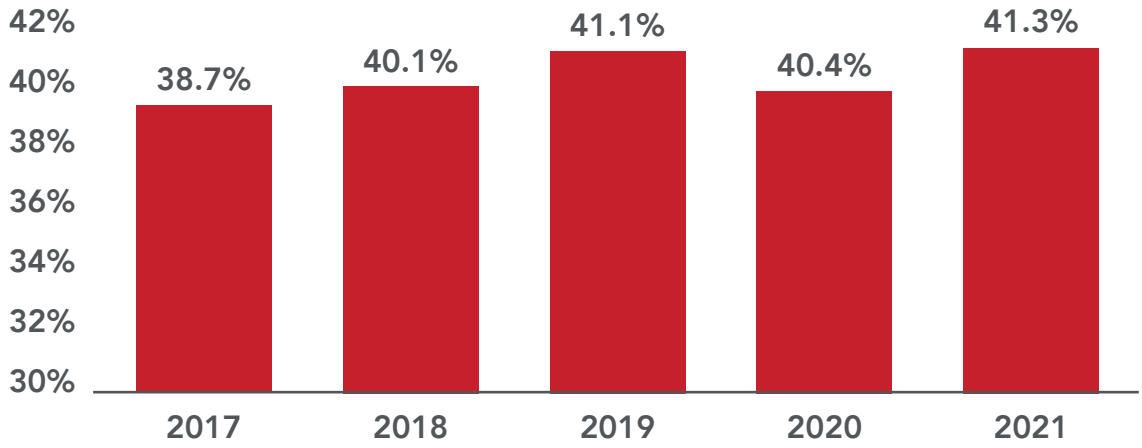
TABLE 5.5 | Disease states prevalence rate for diabetic claimants by number of diabetic medication classes, 2021

Disease State	Diabetes Medication Claimants (By the Number of Diabetes Medication Classes)				
	1	2	3	4	5+
Elevated Cholesterol	48.0%	69.0%	79.1%	85.5%	87.4%
Hypertension	48.9%	66.6%	72.6%	77.7%	78.9%
Infection	31.5%	34.1%	37.1%	39.6%	42.8%
Acid Related Gastrointestinal Conditions	25.1%	28.8%	32.2%	34.1%	37.6%
Pain	25.0%	28.2%	32.0%	35.9%	39.1%
Anxiety/Depression	24.3%	25.0%	26.7%	27.4%	30.0%
Vitamins	15.2%	14.5%	15.0%	17.5%	18.8%
Asthma and COPD	12.7%	13.3%	13.8%	14.0%	15.9%
Osteoarthritis	12.7%	12.8%	13.5%	13.9%	15.4%
Thyroid Condition	12.9%	12.1%	11.9%	11.8%	12.9%
Sexual Disorders	1.1%	1.7%	2.1%	2.6%	3.2%
Eye Conditions	0.4%	0.5%	0.9%	1.2%	1.4%

Extended Health Care

Slightly more than 58,000 diabetes medication claimants utilized extended health care (EHC) services in 2021 which made up 41.3 per cent of the total diabetes medication claimant population (Figure 5.12). The EHC utilization rate among diabetes medication claimants had been rising slowly since 2017 with a drop in 2020 which is attributable to the COVID-19 pandemic.

FIGURE 5.12 | Diabetes medication claimant extended health care (EHC) utilization rate by year, 2017 to 2021



Diabetes medication claimants spent 12 per cent (or $55 million) of their overall 2021 health expenditure on EHC services. On average, each diabetes medication claimant spent $1,200 on EHC services including $256 on CGM/FGM devices that were claimed within the EHC benefit (Table 5.6). Outside of the top five EHC services, diabetes medication claimants had much higher levels of spending and much higher prevalence rates than non-diabetes medication claimants on lancets, stockings, optometric diagnostic services, and braces. Greater use of these services is likely due to diabetes-related complications. For instance, diabetes patients were more likely to receive retinal imaging and optical coherence tomography services than non-diabetes medication claimants, which aligns with the need to monitor the impact of high blood sugar on their eyes.

TABLE 5.6 | Top EHC services in prevalence rate between diabetic and non-diabetic claimants, 2021

		Diabetic Claimants	Non-Diabetic Claimants	
Number of Claimants		**58,000**	**679,000**	
Ranking	**Top EHC Services in Prevalence Rate**	**Contribution to the Average Claimant Cost**		**Relative Difference**
1	Prescription Glasses	$187	$184	2%
2	Massage Therapist	$98	$127	-23%
3	Optometric Services (Medical Items and Vision)	$22	$36	-37%
4	Chiropractor	$68	$86	-21%
5	Physiotherapist	$95	$107	-11%
6	Diabetic Lancets	$6	$0	1,917%
7	Footwear	$30	$30	-1%
8	Stockings	$22	$18	26%
9	Optometric Diagnostic Services	$3	$2	31%
10	Braces	$18	$14	27%
Average Cost per Claimant		**$944** (Excluding CGM/FGM)	**$927**	**2%**

Obesity

Obesity is a chronic disease typically characterized by accumulation of excess body fat which can have a negative impact on overall health and quality of life.* There is a very strong genetic component to obesity with an estimated 70-80 per cent of body mass index (BMI) determined by genes. About one in four Canadian adults are obese, with a higher prevalence among males than females.

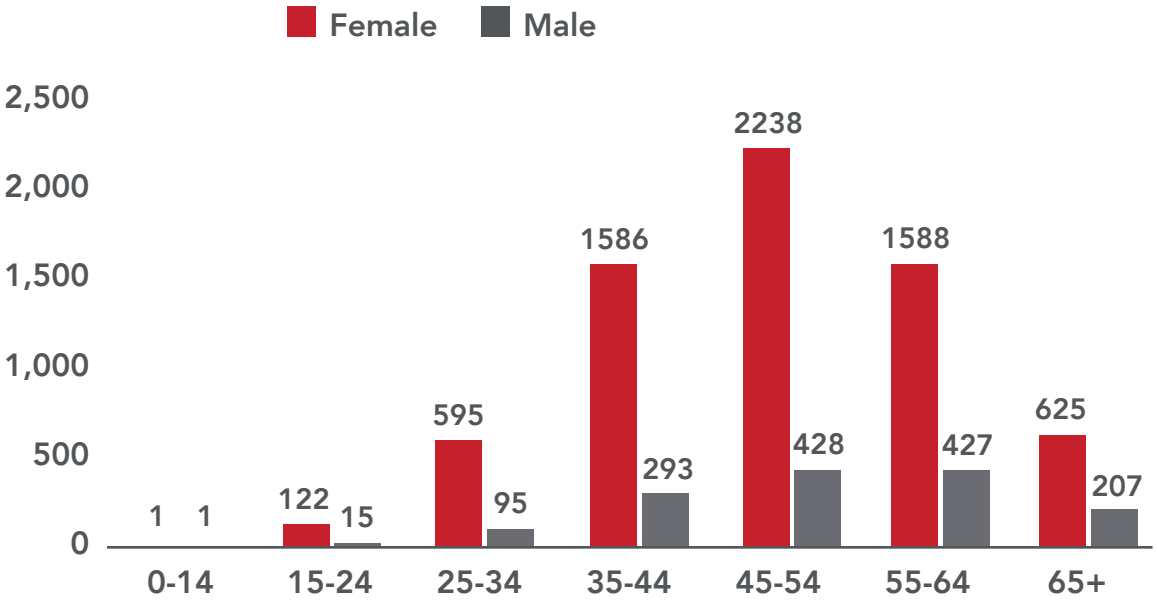
* "What causes obesity?", Obesity Canada website: https://obesitycanada.ca/understanding-obesity/

There is widespread misunderstanding of obesity today, with a common belief that it is purely due to lifestyle factors such as diet and lack of exercise. Unfortunately, this misunderstanding translates into how private drug plans consider obesity treatments, and in particular, anti-obesity drug therapies. Historically, these drug therapies were lumped with smoking cessation and infertility, into a category called "lifestyle drugs." The underlying philosophical assumption has been that these conditions are due to life decisions made by individuals, and as such, the treatments for those conditions should not be reimbursed through benefit plans. Furthermore, even in cases where coverage does exist, the treatments are subjected to a myriad of limitations and restrictions. For instance, it's common to see annual and/or lifetime maximums for anti-obesity treatments even when no such limitations exist for other drugs and treatments. There exists an opportunity to streamline the coverage of these drug therapies to coincide with today's more modern understanding of obesity. HBM+ is currently working on the modernization of this category with more information to follow in the fall of 2022.

From a drug therapy perspective, there are four Health Canada approved treatments: Xenical, Saxenda, Contrave, and Wegovy. Saxenda and Contrave were approved in Canada in 2015 and 2018, respectively, whereas Xenical has been on the market for over two decades. Wegovy was approved by Health Canada in 2021 and is not yet available due to supply issues, though it is expected to reach the market in Q4 2022.

Utilization of obesity medications has escalated substantially in recent years, including a 29 per cent increase in claimants year over year in 2021. Overall, approximately 8,100 HBM+ claimants used obesity medications in 2021 with an average claimant cost of about $1,800. Females over 24 years old represented 81 per cent of the total obesity claimant population (Figure 5.13).

FIGURE 5.13 | Number of Contrave, Saxenda, and Xenical claimants by age and gender, 2021



In looking at comorbidities among obesity medication claimants, mental health was the condition with the highest prevalence rate. Nearly 45 per cent of the obesity medication claimants also used mental health medications in 2021 up by 15 per cent from 2017 (Table 5.7). Use of constipation medications, although not part of the top 10 comorbid conditions, doubled in prevalence during the same reporting period to 17 per cent as constipation was one of the common side-effects of these obesity medications.

TABLE 5.7 | Obesity claimants' comorbid disease states by prevalence rate, 2021

Disease State	Obesity Claimants' Prevalence Rates	Non-Obesity Claimants' Prevalence Rates	Relative Difference
Anxiety/Depression	45%	25%	83%
Infection	41%	33%	22%
Acid Related Gastrointestinal Conditions	34%	20%	68%
Pain	33%	21%	56%
Hypertension	30%	23%	27%
Osteoarthritis	26%	15%	75%
Vitamins	20%	11%	80%
Allergies	20%	13%	55%
Asthma and COPD	19%	12%	59%
Elevated Cholesterol	18%	17%	4%
Constipation	17%	7%	**128%**
Diabetes	13%	8%	**58%**

Cystic Fibrosis

Cystic fibrosis (CF) is a genetic disease that occurs when a child inherits two defective copies of the gene responsible for CF, one from each parent. It is a multi-system disorder that produces a variety of symptoms including persistent cough with productive thick mucus, frequent chest infections, which may include pneumonia, and bowel disturbances among others.* Traditionally, CF was treated mainly with supportive therapies, but over the last decade, a number of drug therapies were approved that treat the underlying cause of the disease, including Kalydeco (2012), Orkambi (2016), Symdeko (2018), and most recently Trikafta (2021). While there have been questions about the efficacy of some of these products and the substantial costs, the treatments have evolved the paradigm of care for CF patients.

The three drug therapies preceding Trikafta have targeted fairly narrow CF populations that have very specific mutations, whereas Trikafta targets a much larger CF population. The larger population, combined with the $306,000 annual treatment cost invites questions about the affordability and sustainability of private drug plans in light of this and other ultra-high-cost drug therapies. There were a total of 100 claimants that used these CF treatments in 2021 with the total drug cost of $14 million, up from 34 claimants and $4.6 million in 2017.**

In addition to these targeted treatments, most CF patients also used other medications to manage their condition including supportive respiratory and infection treatments as well as other supportive treatments such as digestive enzymes (for pancreatic disease), nutritional supplements/vitamins, and hypertonic saline, normal saline, and sterile water (Table 5.8).

* "What is cystic fibrosis?". Cystic Fibrosis Canada website: https://www.cysticfibrosis.ca/about-cf/what-is-cystic-fibrosis

**The analysis in this section does not include Trikafta, which was approved in 2021.

TABLE 5.8 | CF patients' top comorbidities by prevalence rate, 2021

Disease State	Prevalence Rate
Asthma and COPD	94%
Infection	92%
Pancreatic Disease	60%
Vitamins	51%
Fluid/Nutrient Replacement	51%
Allergies	45%
Acid Related Gastrointestinal Conditions	43%
Blood Clot	30%
Endocrine Disorders	30%
Diabetes	26%
Anxiety/Depression	25%
Medical Devices/Equipment – Test Strips	25%
Constipation	23%
Pain	15%
Birth Control	15%

To examine the impact of the targeted CF therapies, HBM+ conducted an analysis looking at the utilization of supporting therapies in the time period one year prior to start and one year post the start of treatment. The objective was to estimate CF disease management using supportive therapies as a proxy for control. The analysis was conducted on a subset of 20 CF patients for whom the complete longitudinal data was available.*

* Claimants were selected if there was at least one claim for a CF disease-modifying drug (Kalydeco, Orkambi, or Symdeko) during the measurement period of January 1, 2017, to December 31, 2020.

The analysis showed that 13 of the 20 patients (65 per cent) had a reduction in the usage of supportive therapies after beginning the use of CF disease-modifying medications, including eight patients (40 per cent) that saw their claims drop by more than 30 per cent with declines across all supportive treatments. Conversely, a small portion of patients experienced greater utilization of CF supportive treatments since starting the CF disease-modifying treatments, with increases in the use of infection, respiratory, and vitamin therapies. While the data is directional rather than conclusive, it suggests that CF patients are generally benefiting from the new targeted therapies and are experiencing fewer complications. Trikafta in particular has a very strong efficacy and safety profile that should lead to substantial improvements in the management of CF.

TABLE 5.9 | Percentage change in number of supportive claims before versus after beginning CF disease modifying treatment

Range of Overall Change	# of Claimants	Infection	Asthma and COPD	Pancreatic Disease	Fluid/Nutrient Replacement	Vitamins
-51%+	4	-80%	-40%	-100%	-86%	N/A
-50% to -31%	4	-51%	-38%	-18%	-39%	-67%
-30% to -11%	4	-36%	-17%	38%	-29%	133%
-10% to 0%	1	-17%	-15%	-9%	7%	43%
0% to 10%	1	-64%	11%	27%	8%	32%
11% to 30%	1	20%	0%	0%	0%	0%
31% to 50%	3	41%	41%	18%	0%	125%
51%+	2	53%	100%	0%	-100%	300%
Total	**20**	**-23.5%**	**-7.4%**	**1.6%**	**-25.7%**	**42.3%**

Drug Pipeline

We continuously monitor the drug pipeline to understand the major therapeutic areas and specific drug therapies that are likely to impact drug plans. This year, we identified three major areas that are expected to be impacted: obesity, COVID-19 treatments, and Alzheimer's disease.

Obesity

Historically, pharmaceutical makers have struggled to develop weight-loss therapies that are impactful and have a side-effect profile that is manageable for patients that utilize them. Recently, however, the pharmacotherapeutic-based treatment of obesity has evolved with the arrival of new anti-obesity drug therapies (Saxenda and Contrave in particular). Interestingly, these therapies promise to be just the beginning of a wave of new treatments that will be hitting the market in 2022 and onwards.

Saxenda is currently the leading product with an average annual treatment cost of about $4,650 and an average weight loss of about five per cent. A follow-on treatment to Saxenda, called Wegovy contains the exact same active ingredient (semaglutide) as a diabetes drug called Ozempic but with a higher dose. Wegovy has a similar price point as Saxenda but with a significantly improved efficacy profile.

The Wegovy clinical trial showed a mean weight loss of 14.9 per cent after 68 weeks. About 70 per cent of patients experienced a 10 per cent or more weight loss and nearly a third of patients achieved a weight loss of 20 per cent or more, which is similar to the levels achieved one to three years after bariatric surgery. Additional benefits noted include a reduction in waist circumference, reduced systolic blood pressure, as well as improved fasting sugar, lipid levels, and C-reactive protein (an inflammation marker). All of this suggests that Wegovy is likely to be a highly utilized product that promises to substantially impact obesity care in Canada and internationally.

Wegovy will be competing with another upcoming diabetes and weight-loss therapy from Eli Lilly called Mounjaro (tirzepatide). Mounjaro was approved by the Food and Drug Administration (FDA) in the United States initially for diabetes in May 2022 but has yet to be approved by Health Canada. (It has been under Health Canada review since February 2022.) Interestingly, Mounjaro has an even stronger efficacy profile compared to Wegovy – phase III clinical trials for Mounjaro have shown weight loss between 15 per cent and 20.9 per cent after 72 weeks. Furthermore, up to 91 per cent of patients reported a weight loss of five per cent or more. Canadian pricing for Mounjaro is unknown at this time but is expected to be in line with Wegovy and other recently approved obesity treatments.

All of these developments suggest that spending on obesity treatments will grow substantially in the coming years but should result in less incidence of other chronic diseases, since obesity is a significant risk factor for many of these diseases, including diabetes, high cholesterol, and hypertension.

COVID-19-related Therapies

Now entering its third year, the global COVID-19 pandemic has had a major impact on health care systems around the world. Tremendous progress, however, has been made in the development of both vaccines and treatments to manage the impact of COVID-19. Vaccination has been a major focus of the efforts to bolster immunity and prevent complications. More recently, however, therapeutics have also been developed to prevent complications of COVID-19 infection. In particular, in January 2022, Health Canada approved Paxlovid for patients with mild-to-moderate COVID-19 at a high risk of developing serious disease, including hospitalization and death. The active ingredient (nirmatrelvir) in Paxlovid works by stopping the virus from replicating.

Paxlovid is the first COVID-19 therapy that can be taken at home. The drug is intended for use as soon as possible after diagnosis of COVID-19 and within five days of the start of symptoms. The treatment consists of two tablets of nirmatrelvir and one tablet of ritonavir taken together twice per day for five days.

From an efficacy perspective, data presented by Pfizer showed that patients (all of whom were unvaccinated) given Paxlovid were 89 per cent less likely to develop severe illness and death compared to trial participants who received a placebo. This suggests a very high level of efficacy that can help reduce the severity of COVID-19 and reduce utilization of health care resources (namely emergency care).

In addition, Pfizer also studied the impact of Paxlovid on preventing infections in people living with someone who had been exposed to the virus. Unfortunately, the clinical trial data presented in April 2022 showed that the treatment was not effective in this context. Those who took the five-day course were found to be 32 per cent less likely to become infected than the placebo group, but the results were not statistically significant.

Private drug plans have been largely shielded from the cost of Paxlovid as the product has been both funded and distributed by the publicly funded health care system in Canada. The process of getting access to the therapy varies by province but in all cases, patients rely on the public system. As the pandemic continues in subsequent years, it remains to be seen how the distribution and funding of Paxlovid, and other future COVID-19 treatments, evolves including the role of private payers.

Alzheimer's Disease

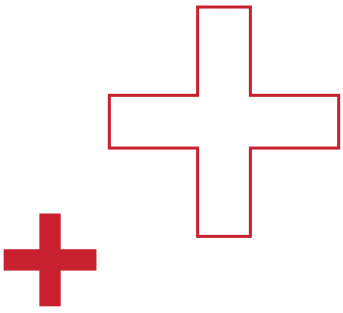
Alzheimer's disease is a very common condition in Canada, particularly among the elderly – over 747,000 Canadians are living with this disease or another form of dementia, with 70,000 individuals newly diagnosed each year. The cause of Alzheimer's disease is not known though it does have an association with age in that people over 65 are at risk, and the risk increases even further at age 85 and older.

In the 2021 HBM+ Drug Trends and Strategic Insights report, we discussed the emerging new treatment for Alzheimer's disease called Aduhelm (aducanumab). In particular, we highlighted some of the controversy that ensued following the approval of this drug in the United States, namely around cost, efficacy, and the integrity of the approval process. Since then, Aduhelm has continued to face significant challenges in the marketplace. It was rejected for funding by major payers, including Medicare and Veterans Affairs in the United States. Medicare's decision was to cover it only for patients who receive the drug as participants in a clinical trial, thereby significantly limiting its reach. In Canada, Biogen (the drug's manufacturer) had submitted the drug to Health Canada for review in June 2021 but then voluntarily cancelled the application in May 2022. This means that Aduhelm will not be available in the Canadian marketplace; this is in keeping with a similar pattern in other countries where Biogen is significantly scaling back or entirely cancelling its efforts to bring the drug to the market.

Interestingly, the lack of success of Aduhelm – with both clinical and marketing challenges – has not slowed pharmaceutical manufacturer interest in this space. At least three other investigational agents are currently in phase III clinical trials expected to be completed in late 2022 – lecanemab (Eisai and Biogen), donanemab (Eli Lilly), and gantenerumab (Roche). The clinical trial programs for all three agents seem to primarily focus on the same surrogate endpoint (an endpoint that does not represent a direct

benefit but rather predicts clinical benefit) – amyloid plaques in the brain. Eli Lilly's product (donanemab) showed promising results in early symptomatic Alzheimer's disease in a phase II trial. The study showed that donanemab reduced brain amyloid by nearly 80 per cent and led to a better score on a composite measure of cognition and daily function, slowing decline relative to a placebo. A phase III trial is underway to validate and confirm these findings on a larger group of patients.

From a timeline perspective, the potential completion of these clinical trials in late 2022 means a submission to the FDA and Health Canada could be forthcoming sometime in 2023 with a potential market entry in the same year. Yet, as was evident with Aduhelm, the successful completion of clinical trials is not guaranteed, nor is payer (public and private) willingness to pay based on questionable efficacy. Alzheimer's disease continues to be an area that generates interest but the pathway to effective drug treatments remains muddied.



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