Drug pipeline: What private plan insurers can expect in 2023.

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Table of contents

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Introduction

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As of January 19, 2023, Health Canada was reviewing 123 drug submissions. Over half of these submissions (76) are for new drugs and the rest are new indications for drugs that are already on the market.

About 13 of the new drug submissions are for cancer therapies. None are expected to have a major impact on private drug plans. Ten of them are intravenous drugs that must be administered in hospital or institutional settings. The remaining three are oral drugs, but similar existing ones will mute their impact: the expense would be the same for existing therapies. That said, this news highlights the strides made in cancer therapy, adding months to the lives of patients, many of whom are of working age.

That leaves about 63 pipeline drugs for consideration, and more from the longer-term perspective. TELUS Health has identified three drugs worth exploring based on their potential impact on private drug plans: one for diabetes and two for migraine.

In the rare-disease space, Hemgenix was approved by the U.S. Food and Drug Administration (FDA) in November 2022 for the treatment of hemophilia B. With a price tag of US $3.5 million for a one-time treatment, this gene therapy has taken over the title of the most expensive drug in the world. While Hemgenix has not yet been submitted to Health Canada, it is worth monitoring for its price alone.

Lastly, the 2023 edition of the TELUS Health Drug Pipeline report summarizes what private drug insurers can expect for generic and biosimilar drugs. Three biosimilar drug submissions are expected this year and a host of generic entries should provide some cost relief for plan sponsors, particularly in the diabetes category.

What to expect

Diabetes

Drugs and devices to treat diabetes account for 12% of the total eligible number of claims submitted to private drug plans for coverage, according to the 2022 TELUS Health Drug Data Trends & National Benchmarks report. The category ranked second on the top-10 list by eligible amount, close behind rheumatoid arthritis (12.6%) but well ahead of the third-ranked category, skin disorders (7.7%).

Results over five years show that diabetes drugs and devices have steadily increased their share of the total eligible amount, from 9.2% in 2017 to 12% in 2021. Their share of claims has climbed from 6.6% to 7.7% over the same period.

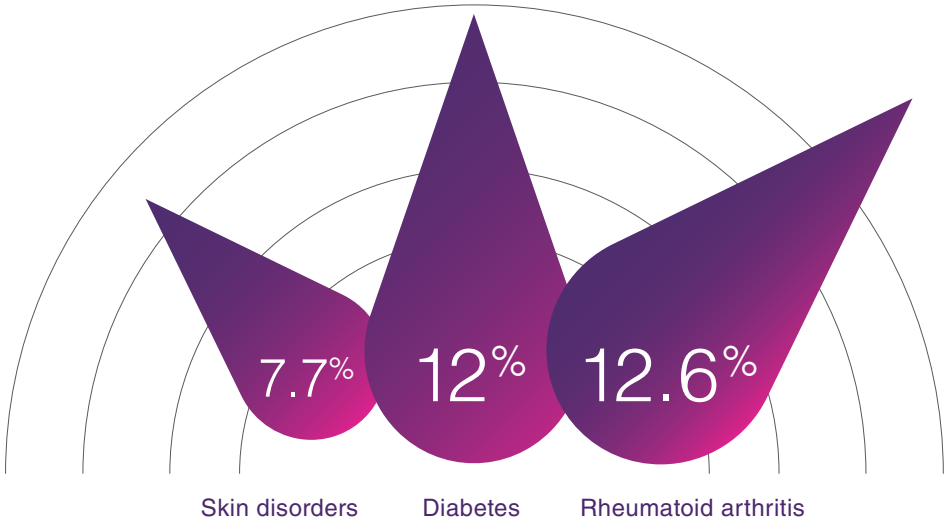
The growth in utilization can be attributed in part to a growing patient population. Research captured in the 2020 report 100 Years of Insulin – Diabetes in Canada revealed that 10% of Canadians (about 3.8 million) were living with diagnosed type 1 or type 2 diabetes in 2020, compared to 6.8% in 2008.[1] More recent analysis by Diabetes Canada places the prevalence rate at 10.2% in 2022 (more than four million Canadians), increasing to 14.5% (5.7 million) with the inclusion of undiagnosed type 2 diabetes and to 29.8% with the inclusion of prediabetes (a condition that, when not managed, can develop into type 2 diabetes).

Second-line therapies are a key driver of growth in the diabetes category. Several classes of second-line therapies for type 2 diabetes emerged over the past decade, with strong uptake year after year. These drugs have also proven popular due to their positive impact on weight loss.

The average annual eligible amount for some second-line therapies can be between $1,000 and $2,500, compared to about $120 annually for metformin, the first line of therapy for type 2 diabetes.

For private drug plans, some cost relief is in sight as patents expire for the oldest second-line therapies. Over 30 generic options may become available by the end of 2023 (see details on page 14).

What about today's pipeline? Only one new diabetes drug is expected this year: Eli Lilly's Mounjaro (tirzepatide), a weekly self-injection for type 2 diabetes approved by Health Canada in November 2022, with an expected market launch early in 2023. The FDA approved it in May 2022.

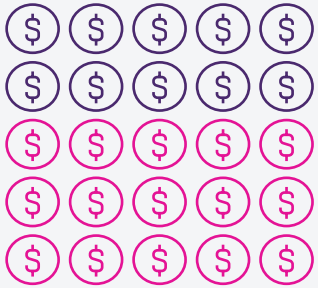


Total eligible number of claims submitted to private drug plans for coverage.

The average annual eligible amount.

Some second-line therapies.

Between $1,000 and $2,500



Metformin - first line of therapy.

About $120 annually

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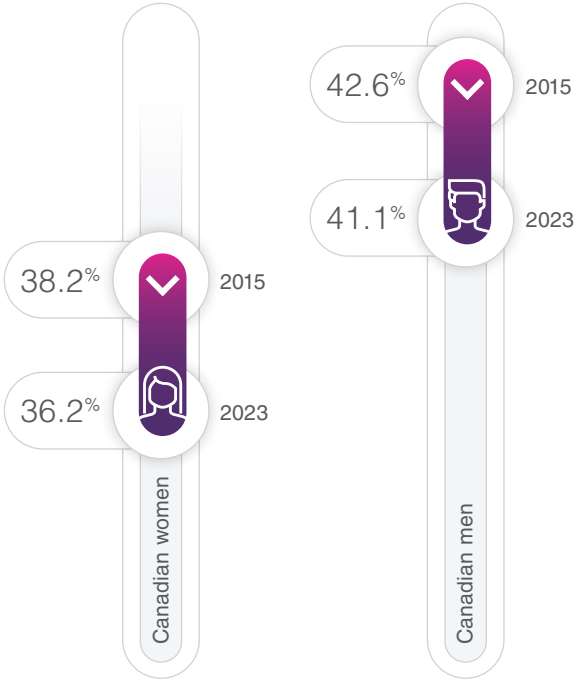
Potential **impact of Mounjaro** on private drug plans.

About $2,500 to $3,000 annually

Canadians that cannot reach their targets for blood-sugar levels.



Mounjaro is another new class of second-line therapy, combining a GIP (glucose-dependent insulinotropic polypeptide) with a GLP-1 agonist (one of the current classes of second-line therapies). Both components are hormones involved in blood sugar control. In clinical trials, Mounjaro has proven superior to today's most prescribed GLP-1 agonist, Ozempic (semaglutide), for both blood-sugar control and weight loss.

TELUS Health predicts the potential impact of **Mounjaro** on private drug plans to be high, given the potential patient population and anticipated annual treatment cost of about $2,500 to $3,000. Considerable off-label use in weight loss is also expected, based on the current off-label use of Ozempic and Victoza, another second-line diabetes therapy.

Looking ahead, Novo Nordisk, the manufacturer of Ozempic—for which data protection is expected to expire in 2026—is investigating a once-weekly injection that combines Ozempic's semaglutide with cagrilintide, a hormone that results in weight loss by inducing satiety. Phase 2 trial results from Denmark showed a modest improvement in blood-sugar control and much higher weight-loss results than with Ozempic alone. Phase 3 trials begin this year, and TELUS Health expects the new formulation to be submitted for Health Canada review in time for it to receive approval prior to Ozempic, which will likely lose exclusivity in 2026.

It's important to keep in mind that updated clinical practice guidelines recommend second-line diabetes therapies when patients cannot otherwise reach their targets for blood-sugar levels. A 2023 research paper found that 36.2% of Canadian women and 41.1% of Canadian men had not reached their target levels in 2020, which indicates that a large proportion of patients will be eligible for the second line therapies.[2] The good news is that these results signal an improvement over 2015, when 38.2% of women and 42.6% of men were not reaching their target levels. The study's authors stated that "the improvement … may reflect the increasing availability of hypoglycemia-neutral and weight-favourable medications [i.e., second-line therapies]; however, the prescribing of these agents can still be improved."

What to expect

Migraine

Many people who struggle with migraines eagerly await the launch of **Ubrelvy** (ubrogepant) by AbbVie, the first new drug to treat migraine attacks since the launch of triptans, today's go-to medications, in the 1990s. Ubrelvy was submitted to Health Canada in October 2021 and approved in November 2022. The FDA approved it in December 2019, almost two years before AbbVie submitted it to Health Canada.

Ubrelvy is part of the new class of migraine drugs called CGRPs (calcitonin gene-related peptide inhibitors), which first became available in Canada in 2018. CGRPs are indicated for patients who are hardest hit by migraines, namely those with episodic (between four and 14 a month) or chronic (15 or more a month) migraines.

The pricing of Ubrelvy in Canada will likely be similar to that of branded triptans such as Axert, Imitrex and others, at $15-$16 per tablet. It will be considerably more expensive than generic triptans, which are less than $10 per tablet. The total annual cost will vary based on patients' needs. For a person using it to treat four migraines a month (the minimum for a diagnosis of episodic migraine), the estimated cost would be about $720 a year. For someone suffering from 15 migraines or more a month, the annual cost could exceed $3,000.

The estimated prevalence of migraine in Canada is 8.3%, or almost 3.3 million Canadians.[3] About a quarter of those—or 825,000—meet the criteria for CGRPs. In the four years since the launch of the first CGRP, this drug class has steadily accelerated its growth rates for both costs and claimants in the overall migraine category.

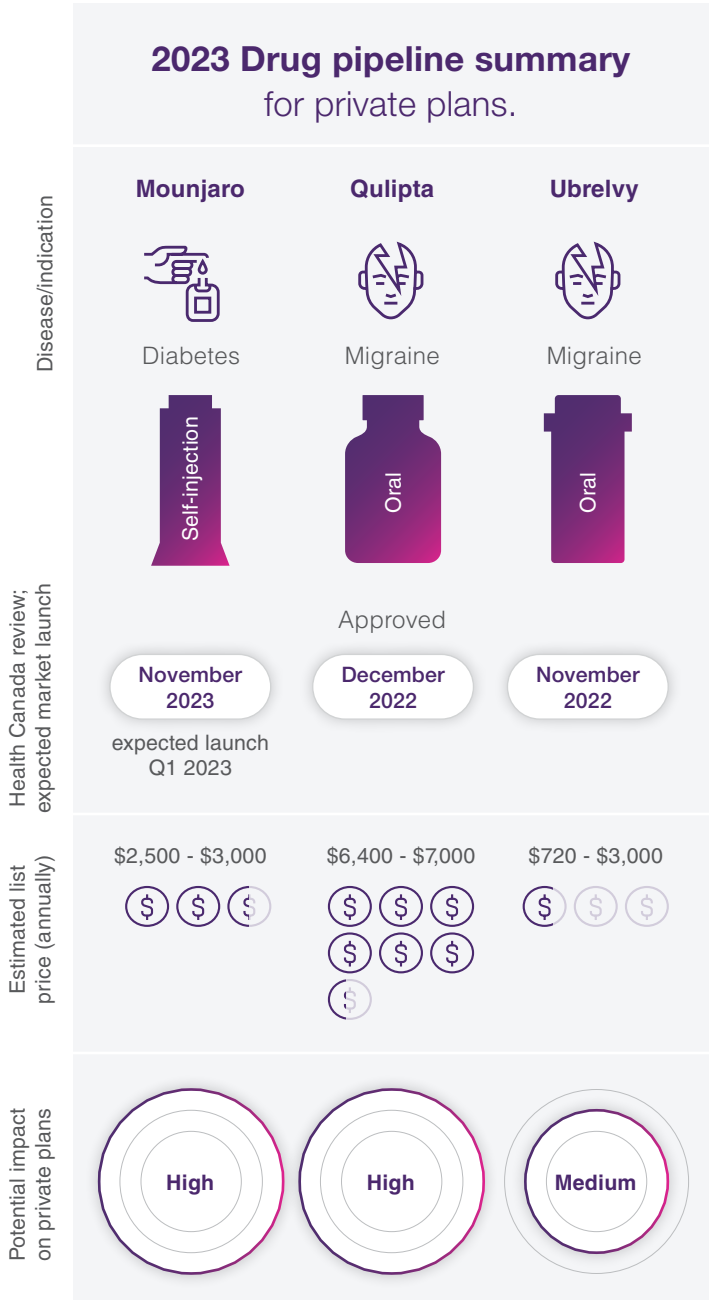
What distinguishes Ubrelvy from other drugs is the fact that it is the first CGRP to treat migraine attacks, whereas the others are prescribed for the prevention of migraine. It is also an oral tablet, while the others require injection.

TELUS Health predicts a medium potential impact on private plans. On the one hand, Ubrelvy joins a mature, heavily genericized market for triptans, and its pricing is reasonable. On the other hand, it is the first new treatment option in decades for migraine attacks. While its efficacy compared to triptans remains to be seen, Ubrelvy has fewer side effects and could be better tolerated, which may prompt new users.

AbbVie will also roll out Qulipta (atogepant) this year for migraine, approved by Health Canada in December 2022. It received approval in the U.S. in September 2021.

Qulipta joins existing CGRPs for the prevention of episodic migraine—yet it also stands apart as the first preventative CGRP in tablet format. The others are administered by self-injection. This potentially makes it attractive for people who are needle-averse, or who prefer the convenience of a pill over an injection device. The cost of Qulipta in Canada will likely be similar to its competitor products, or about $6,400 to $7,000 annually.

TELUS Health expects that Qulipta's impact on private drug plans will be potentially high, given that the CGRP inhibitor market for prevention is still growing and patients will likely be attracted to the convenient tablet format.



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What to expect

Cancer

Cancer drugs continue to dominate drug pipelines around the world. Analysis by GlobalData indicates that they have come to consistently account for about a third of all drugs in the latter stages of development (phases 2 and 3). Many of the submissions involve new indications for existing drugs (such as treating additional types of cancer), or new drugs that provide incremental improvements over existing drugs.

Despite the level of product development, private plan insurers see relatively little of the action since many cancer drugs are administered in hospitals or other medical institutions. While oral cancer drugs are on the rise—opening the door to coverage by private plans—, no high-impact oral cancer therapies are in Canada's short-term oncology pipeline at this time.

Looking ahead, researchers are hopeful about **fadraciclib**, currently in phase 2 trials. Early results for this oral drug are promising for both blood cancers (leukemias) and solid tumours (lung, breast, etc.). However, it will likely be several years before clinical trials end or are at the point where a decision is made to proceed with a regulatory review.

While non-oral cancer drugs have little direct impact on spending by private drug plans, they could have an indirect positive impact on disability claims and workplace productivity. Relatlimab for late-stage melanoma, currently under review by Health Canada, has been shown to add five months or more to patients' lives during which the disease does not progress, for an average progression-free survival period of just over 10 months.

Another interesting area of research for cancer therapy is an mRNA vaccine combined with Keytruda, an immunotherapy agent, to reduce the risk of cancer recurrence. As reported by CNN in December 2022, preliminary results of a study involving post-surgical patients with melanoma indicated a 44% reduction of cancer recurrence or death risk. While immunotherapy is typically provided by public plans, this research illustrates the broad range of possible future applications for mRNA vaccine technology, which rose to prominence during vaccination campaigns for COVID-19.

What to expect

Hemophilia

With a list price of US $3.5 million for a one-time treatment, **Hemgenix** (etranacogene dezaparvovec) has become the world's most expensive drug. Approved by the FDA in November 2022, the gene therapy is considered a breakthrough treatment for hemophilia B, which accounts for about 15% of patients with hemophilia. In Canada, the Canadian Hemophilia Registry reports a patient population of about 650.

It's expected that manufacturer CSL Behring will submit the drug to Health Canada for review in the coming months.

As reported by Bloomberg, a two-year clinical trial found that, for nine out of 10 patients, the one-time treatment eliminated the need for continuous, costly and time-consuming infusion therapy.

The Institute for Clinical and Economic Review noted that current infusion therapy to prevent bleeding associated with hemophilia "is widely considered to be far too expensive to be cost-effective." Its cost-effectiveness model for Hemgenix and another gene therapy for hemophilia A "shows health gains and the potential for substantial cost offsets due to elimination of the need for very expensive prophylactic treatment." The model calculated a reasonable price point of about $2.9 million for Hemgenix.

Patients in Canada will likely look to public payers for reimbursement of Hemgenix, as is the case for current hemophilia treatments. If so, there would be no impact on private plans.

Also, for hemophilia, Novo Nordisk has submitted **concizumab** (brand name to be announced) to Health Canada, and approval may occur around the third quarter of 2023. Phase 3 trial results have shown significant reductions in spontaneous and traumatic bleeds for both hemophilia A and hemophilia B patients.

A biologic drug, concizumab will not be nearly as costly as Hemgenix, the gene therapy. The good news for private plans is that, even though concizumab can be administered by self-injection, funding will likely be sourced through public agencies, as with all other hemophilia treatments.

What to expect

Generics

Industry analysts predict the “next big patent cliff” is rapidly looming with the loss of market exclusivity for a number of blockbuster drugs, including biologics. Among non-biologic traditional drugs, private drug plans will experience the biggest impact in the diabetes and attention deficit hyperactivity disorder (ADHD) categories.

Drugs to treat diabetes and ADHD rank second and sixth, respectively, on TELUS Health’s top-10 list of categories by eligible amount.

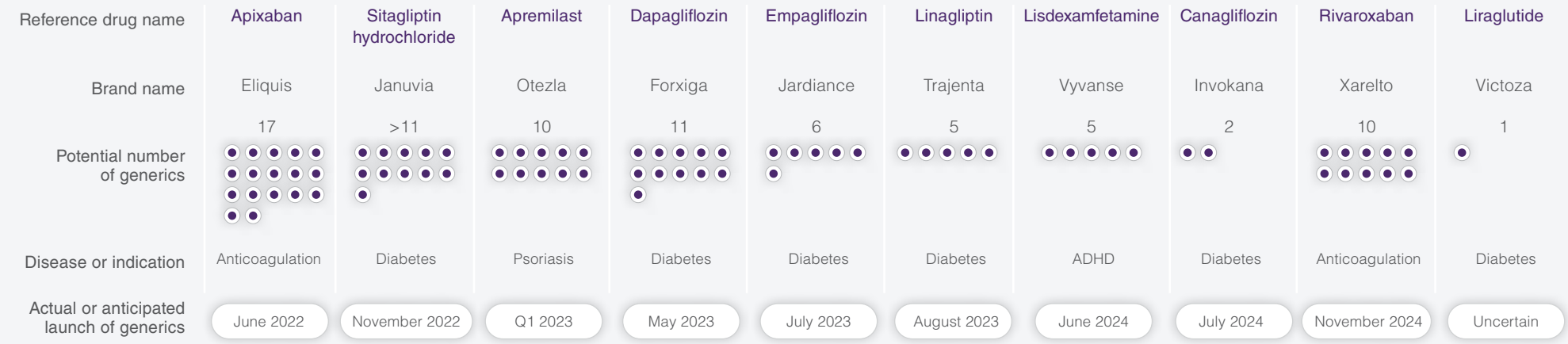
The drugs with patents expiring in the diabetes category are second-line therapies with an annual eligible amount per claimant of at least $1,000 annually. By the end of 2024, 36 or more generics may become available as alternatives to the six branded diabetes drugs that will no longer be patented. Based on the current pan-Canadian Generic Tiered Pricing Framework, which expires in March 2023 and is currently under renegotiation, the generic equivalents would be priced at 25% (for three or more generics) or at 50% (for two generics) of the brand-name price for oral drugs, and at 35% (for three or more generics), or at 50% (for two generics) of the brand-name price for injectable drugs. For example, generics for Januvia will be priced at 25% (about $250 annually) of its brand-name price (about $1,000 annually).

However, it’s worth noting that data protection for Ozempic, which dominates one of the classes of second-line therapies for diabetes and is on TELUS Health’s top-10 list of all products by eligible amount, has not yet expired. That is expected to happen in 2026.

Generic options for Vyvanse to treat ADHD should generate considerable cost savings for private drug plans. Vyvanse is on the top-10 list of products covered by private drug plans based on eligible amount, and five generic alternatives are currently under review by Health Canada. With that many generics, pricing would be at 25% of the branded product, according to the current Generic Tiered Pricing Framework. Generics for Vyvanse are expected to become available in June 2024. A federal court decision prevents an earlier launch.

In the specialty non-biologic space, generic options for Otezla for psoriasis are poised to become available by spring 2023. Eight generics have already been approved and two more are under review at this time, which means pricing would be at 25% of the brand-name oral drug in provinces where Otezla is listed on the public plan. The Canadian list price of branded Otezla is about $13,800 per year, suggesting generic prices of $3,450 to $11,730, depending on the province.

New generic drugs, by launch date.



What to expect

Biosimilars

New biosimilar drugs, by anticipated launch date.

Three biosimilars are expected to launch this year or early in 2024. Two are for macular degeneration, which affects about 2.5 million Canadians (6.4%) and is the leading cause of vision loss in people older than 55.[4]

In March 2022, Health Canada approved Byooviz (ranibizumab), Canada's first biosimilar for macular degeneration. The originator biologic is Lucentis. Market launch is expected early in 2023 and the list price for Byooviz will likely be 35% to 40% lower than the price for Lucentis.

Health Canada began its review of the first biosimilar for Eylea (aflibercept) in May 2022. The anticipated launch of this biosimilar for the treatment of macular degeneration will likely occur by June 2024. Numerous additional biosimilars are in various stages of clinical trial development.

A biosimilar for Soliris (eculizumab), previously considered the world's most expensive drug, could be approved by Health Canada by mid-2023. Soliris treats an extremely rare, life-threatening blood disease that affects one to 10 people per million. The average annual cost is about $700,000.

Looking ahead to 2024, anticipation is building for biosimilar options for Stelara, which ranks high on the list of top products covered by private drug plans based on eligible amount. Stelara treats Crohn's disease, ulcerative colitis, psoriasis and psoriatic arthritis.

Conclusion

Developments in the diabetes category will have the biggest impact on private plans this year and in the near future, for two opposite reasons: on the one hand, new higher-cost second-line therapies continue to arrive on the market; on the other hand, dozens of generic versions of the oldest of these second-line therapies will become available, starting this year.

While generic drugs are good news for drug plans, the extent of savings generated by generic second-line diabetes therapies may be limited at first since they are for the oldest, less-utilized medications. It will be several years yet before the expected patent expiry of the most prescribed second-line diabetes therapy, Ozempic. Meanwhile, product life cycle management for Ozempic is well underway, as a new version of the drug—with even better weight-loss outcomes—is expected to launch before the current patent expires.

The weight-loss benefits of the second-line diabetes therapies, which have led to off-label prescribing of these drugs, help drive the category's growing share of total eligible amounts covered by private drug plans. Diabetes ranked second on TELUS Health's top-10 list of categories by eligible amount in 2022, and it is poised to take over the number-one spot.

The two new drugs for migraine are worth watching. As the first two oral options in a new class of migraine drugs, their overall utilization may grow among patients who have avoided the original injectable drugs. Indicated for those who are hardest hit by migraines, these drugs could lead to increased productivity and fewer sick days in the workplace.

In the biologic space, biosimilar options slowly but steadily grow in number. For drug plan insurers with biosimilar switching policies in place, the savings could be significant. This year will see the first biosimilar for macular degeneration. As well, at least one biosimilar for Soliris, which made headlines in 2007 as the world's most expensive drug, will become available.

References

1. Norris, S. 100 Years of Insulin - Diabetes in Canada. Library of Parliament. Research Publication No. 2021-29-E. 2021 Dec.
2. Nandiwada S, Manca DP, Yeung RO, et al. Achievement of treatment targets among patients with type 2 diabetes in 2015 and 2020 in Canadian primary care. CMAJ. 2023 Jan 9;195:E1-9. doi: 10.1503/cmaj.220673
3. Ramage-Morin PL, Gilmour H. Prevalence of migraine in the Canadian household population. Statistics Canada. Health Reports. 2014 Jun; Catalogue no. 82-003-X.
4. Moniz L, Andrews C, Pereira J. Canadian patient experience with age-related macular degeneration. IOVS. 2022 June;63(7):4226-A0154.

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