The PLAN SPONSOR'S guide to drug formularies and prior authorization

Not all drug formularies are created equal

PRESENTED BY:

Benefits CANADA

ART WITH FILES FROM ISTOCK (INVINCIBLE_BULLDOG, APPLEUZR)

OVERVIEW

ISTOCK/ SPXCHROME

1. Introduction

Drug plan costs are a major concern for plan sponsors. Because of this, most plan sponsors are looking for ways to ensure their health benefits are sustainable, attract and retain top talent and provide coverage for the drugs plan members need. This guide will review best practices for group benefits formulary management and prior authorization to ensure appropriate coverage and minimize plan sponsor risks.

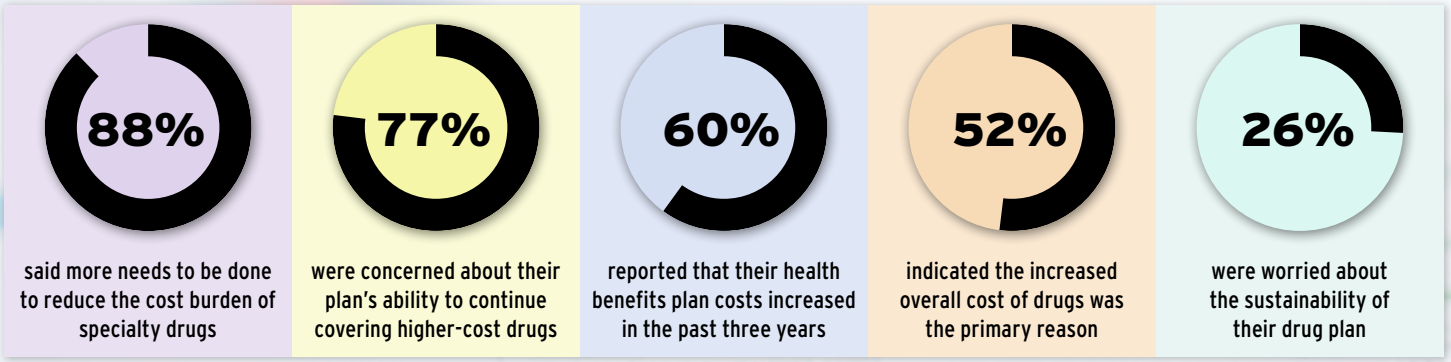
There are a wide variety of plan designs that can control drug claims cost. However, managed formularies can be a strategic solution; when properly implemented, these can optimize drug utilization, enhance cost effectiveness and include high-value medications instead of blunter tools (i.e., plan maximums or delisting). Managed formularies allow plan sponsors to balance coverage, cost effectiveness, budget and positive health outcomes.

Medavie Blue Cross analysis illustrated the benefit of managed formularies. In 2023 the average eligible claim amount for non-managed plans grew 4.5% compared to managed plans (3.7%) during the same period.[1]

Plan sponsors choose and pay for the health benefits plan design that best meets their needs, which includes choosing a formulary. Although plan sponsors select a payer to manage their drug plan, they're still responsible and potentially liable for how their payer manages both the drug plan and formulary.

Private plan costs are driven by claims–and in 2023 drug claims cost increased 5.9%. This was due to the growth of speciality drug claims (3.7%), as well as the growth of traditional drug claims (7.0%). Although specialty drugs represented 33% of total claims cost, they represented only 1% of claims.[1]

Drug plan costs are a major concern for plan sponsors and according to the 2023 *Benefits Canada* plan sponsor health-care survey:[2]



123RF/ CHORMAIL

2. Plan sponsor obligations and responsibilities

In addition to the financial liability that comes with a health benefits plan, there are many lesser-known but equally important risks that must be considered. Even if formulary management is delegated to a third party, plan sponsors may still be accountable for their coverage decisions.

"With respect to the benefits they arrange for their employees, plan sponsors can ultimately be held accountable for discrimination, misrepresentation, noncompliance with a collective agreement and other grounds," said Mitch Frazer, managing partner, Mintz LLP Toronto.

Health benefits form part of employees' employment and compensation agreements, which are separate and distinct from the insurer's benefits contract and booklet. Benefits coverage is communicated to plan members in several ways, such as offer letters, correspondence, company websites or collective bargaining agreements.

"Plan sponsors may face legal liability for declined claims when the formulary administration doesn't align with employee communication materials or collective bargaining agreements," said Philippe Lagacé, principal, health and benefits, Mercer Marsh.

If the insurer pays claims as per their contract with the plan sponsor, but the coverage deviates from what the plan member was promised, the plan sponsor may be liable for the claim even if the insurer isn't.

> "Plan sponsors may face legal liability for declined claims when the formulary administration doesn't align with employee communication materials or collective bargaining agreements."
>
> — Philippe Lagacé
> principal, health and benefits, Mercer Marsh

Human rights obligations

Provincial employment, accessibility and/or human rights legislation generally states employees have a right, with respect to employment, to equal treatment without being discriminated against because of a disability, explained Frazer. "However, there are limits to the content of that right... the employer's duty to accommodate an employee who has a disability extends only to the point of undue hardship." Legislation may also provide exceptions permitting benefits plans to discriminate in specific circumstances like pre-existing disabilities.

Depending on the situation, non-coverage or denial of a drug—for a particular person with a particular disability—could be discriminatory, said Frazer. "Benefits plans are necessarily limited in many ways and plan sponsors aren't required to provide unlimited coverage." Any decision to limit the scope of benefits coverage will affect some employees less favourably than others. But if the decision to limit certain drug coverage is because of/based on an employee's disability, the plan sponsor may be found to have illegally discriminated against that employee.

Another potential area of liability is granting coverage exceptions for plan members. If plan sponsors are regularly considering ex-contractual exceptions, they're potentially vulnerable to challenges about plan equity. According to Frazer, where a plan sponsor makes ex-contractual exceptions for some employees but not others, those whose requests have been denied may wonder if the denial was due to a protected characteristic about themselves. "Plan sponsors who make such exceptions should have a well-documented and established process for doing so. This will ensure protected factors do not improperly influence decision-making."

Plan sponsors have a fiduciary responsibility for the vendors they select to deliver health benefits, which includes formulary management. A plan sponsor may also have a fiduciary obligation to plan members, said Frazer, meaning the plan sponsor must act in their employees' best interest. However, the existence and nature of that duty will depend on the circumstances. "Plan sponsors should be cautious when making/ignoring changes to their coverage or carriers, especially if they're aware that such changes may adversely affect an employee. In this case, a plan sponsor may owe a fiduciary obligation to protect that employee's interests."

> "Plan sponsors should be cautious when making/ignoring changes to their coverage or carriers, especially if they're aware that such changes may adversely affect an employee. In this case, a plan sponsor may owe a fiduciary obligation to protect that employee's interests."
>
> Mitch Frazer
> managing partner, Mintz LLP Toronto

Beyond legal risk

Beyond the legal risks, reputational and credibility risk are also important to consider. Plan sponsors need to think about the impact of plan members who are denied coverage—and the possibility of them bringing their stories to the media.

As workplaces continue to implement diversity, equity and inclusion policies and approaches in their workplaces, it's important that they also ensure their drug plan is aligned. Do the covered drugs meet the needs of their diverse workforce and are they inclusive and equitable for all?

3. Formulary management

In its simplest form, a formulary is a list of covered drugs. But like many health benefits plan components, the devil's in the details.

When selecting a health benefits plan, plan sponsors choose a formulary and a payer/formulary manager that determines the drugs included in the formulary. This is similar to how mutual funds are handled: the customer chooses a fund aligned with their investment philosophy and risk tolerance but rely on the fund manager's expertise to choose the stocks.

Different formulary models exist, and the choice depends on the plan sponsor's unique philosophies and objectives. Each payer offers multiple formularies, ensuring a range of selections to meet different plan sponsor's needs.

"There's no one-size-fits-all solution," said Lagacé. It depends on the plan sponsor's goals, philosophy, budget, public programs and constraints. Generally, there needs to be effective clinical and economic drug evaluation. There also needs to be integration support with other funding sources.

Each payer has their own philosophy and process to manage formularies. Even formularies that appear to be similarly named are usually different when it comes to the actual drugs covered or the process for assessing new drugs. As a result, choosing a managed formulary can have an impact on the plan's portability because when switching from one payer to another, a different type of managed formulary will be set in place.

A payer's drug review committee normally assesses new drugs—ideally based on clinical effectiveness, cost effectiveness and financial impact. However, each committee might come to a different decision depending on the evidence they consider and their value-assessment perspective.

Nina Lathia, health economics consultant and founder and CEO of Healthcare Decision Making, recommends private payer drug review committees use a systematic, evidence-based process that's applied consistently to all decisions. She also recommends these committees consider clinical effectiveness, cost effectiveness, safety and adverse effects, health-equity implications, as well as patient and plan member preferences.

"When properly constructed, formularies are a crucial strategy for keeping prescription medications affordable while preserving access for plan members who need them," said Lagacé.

123RF/ MARKOLPAKOV, VLADYSTOCK

4. Time to listing

There are a variety of factors that influence the timely listing of new drugs. As new drugs become increasingly complex, so do their reviews. Some delays can be attributed to the time required to negotiate a product listing agreement (PLA) between the private payer and the pharmaceutical manufacturer.

According to a survey of Innovative Medicines Canada's member companies,[3] private payer drug reviews can take as long as seven to 12 months; and reviews for more complex drugs or those that treat rare diseases can take longer than 13 months. Private payers that rely on public drug plan recommendations may see a slower time to list compared to payers who conduct in-house assessments. These delays can lead to the deterioration of plan members' health or new/continued disability claims.

> Private payer drug reviews can take as long as seven to 12 months; and reviews for more complex drugs or those that treat rare diseases can take longer than 13 months.
>
> — Survey of Innovative Medicines Canada's member companies

5. Assessing a drug's value

123RF/ NEXUSBY

Formulary decision-making based solely on drug-acquisition cost doesn't consider the value the drug may provide to the ultimate payer: the plan sponsor. Evaluating a drug shouldn't just hinge on its cost. It should consider the impact of an untreated condition that could progress and how that could affect productivity, absenteeism and disability. With private drug plans, it's also important to consider the impact on plan members who are caregivers—and what will happen when their spouse or child doesn't have access to medication they need to manage their condition.

Pharmacoeconomic reviews allow drug plan managers to assess if a new drug's benefit is worth the increased cost. It's important that new drug submissions—sent by pharmaceutical companies to insurers—include data that demonstrates the value their drug has to a private plan sponsor.

6. Getting the perspective right

Some private formulary managers reference government drug assessments and recommendations to inform their formulary management. Although following government decision-making may seem easy, it can add unnecessary delays and might not align with private plan sponsors' philosophies.

The Canadian Agency for Drugs and Technologies in Health (CADTH) reviews drugs for most Canadian provincial drug plans and adopts a public payer perspective. They conduct clinical reviews and assess the cost effectiveness and budgetary impact of a drug on the public system—compared to private payers' focus on absenteeism, disability and productivity. Additionally, because demographics for public plans are different than employer-sponsored ones, the value assessment must be different. An Innovative Medicines Canada survey of member companies noted private payers use public plan reviews to inform their drug evaluations almost 60 per cent of the time.[3] Because public drug plans take much longer to list new drugs, private payers who rely on the public's recommendations may see a slower time to list compared to private payers who conduct their own assessments.

"Public payer recommendations can provide a reasonable baseline for private payers to begin their assessments, but they shouldn't be used as the only source of information," said Lathia. Public payers typically exclude productivity costs, which are important to plan sponsors; they also include costs that can be irrelevant to employers like those included in the publicly funded health-care system (i.e., hospitalization and physician fees). "As such, from a private payer's perspective, public payers could potentially provide a skewed value assessment, leading to suboptimal reimbursement decisions."

> Public payers typically exclude productivity costs, which are important to plan sponsors; they also include costs that can be irrelevant to employers like those included in the publicly funded health-care system (i.e., hospitalization and physician fees).
>
> — Nina Lathia
> health economics consultant and founder and CEO, Healthcare Decision Making

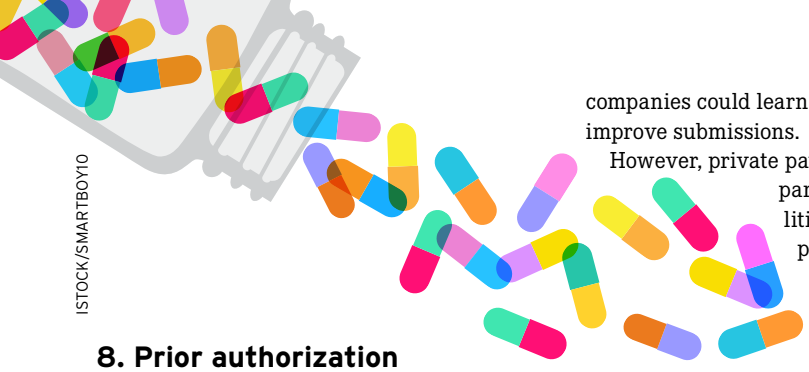
Conducting a private payer-focused drug value assessment is different than integrating private coverage with public coverage, which generates savings for plan sponsors. Some formulary managers may look to government decision-making in pharmacare provinces so they can effectively coordinate private coverage with public drug plans.

In addition to the value of a medication, private plans need to consider affordability. "Affordability should be assessed based on the absolute cost of the drug, the number of potential patients receiving the drug, the comparative efficacy and safety of the drug to other available treatments, as well as the comparative cost of the drug relative to typical drug plan spend," said Lagacé.

7. Transparency

Public drug plan timelines, assessments and outcomes are published, allowing stakeholders to understand the rationale for drug coverage recommendations. However, there isn't similar transparency for private plans. "The lack of drug review status updates or outcomes can be frustrating for all stakeholders involved—and transparency in these processes could lead to improved trust and understanding," said Richard Sist, managing partner, Resist Financial.

The more transparency, the better, said Lagacé, noting plan sponsors are being challenged by members to provide rationale for coverage decisions. If a plan member or plan sponsor wants to better understand why a drug isn't covered, there are no published reviews that can be referenced. If reviews were made public, stakeholders could better understand the criteria and rationale used to make drug coverage decisions and pharmaceutical



ISTOCK/SMARTBOY10

companies could learn from prior reviews to improve submissions.

However, private payers face unique transparency challenges like litigation risk and competitive disadvantages. According to Frazer, such determinations are fundamental to a private payer's business—and these determinations rely on cost control and accurate forecasting to ensure coverage cost is aligned with the premiums received for that coverage. "To the extent possible, private payers will protect those complex and proprietary decision-making processes and outcomes."

8. Prior authorization

Prior authorization (PA) is a tool used to facilitate formulary decision-making at the individual plan member level; it's usually the outcome of a formulary drug review process, including open formularies. When a drug coverage decision is made, instead of determining if it's covered or not, PA allows payers to gather patient-specific information to assess whether coverage is appropriate. It can also be a risk-mitigation strategy around appropriate use, utilization, off-label prescriptions, dosage escalation and fraud, as well as a tool to assess ongoing treatment value on a patient-by-patient basis. Carrier and drug-specific PA forms are needed to gather patient-specific data that can't be collected through the pay-direct drug adjudication process. According to Medavie Blue Cross, 99.9% of their drugs plans have a prior-authorization process.[1]

PA is not a stand-alone process—rather, it's part of a payer's comprehensive toolbox of drug plan management tools. If PA is extracted from the formulary management process as a separate program, there are potential plan sponsor risks. (see External Drug Plan Managers)

An individual payer's specific criteria should be a standardized, unbiased guideline for equity and consistency. However, given the differences in each payer's formulary and philosophies, it's impossible to standardize criteria across the industry.

Plans that deny coverage based on seemingly arbitrary criteria are at greater risk of unintentionally imposing a discriminatory effect on a plan member. "Best practices should involve clearly documented and reasoned criteria for authorizations—and standardization, to the extent possible, can be a helpful component of the process," said Frazer.

A drug plan's portability can be impacted by a payer's own PA criteria. When the plan switches payers, their drug-specific PA criteria may also change.

Simplify Prior Authorization

After the release of a 2020 comprehensive report on private payer prior authorization in Canada, the Simplify Prior Authorization (SPA) initiative was created to advocate for improvements in the prior-authorization claims process. Since then, SPA has shared new insights into PA and the opportunities for improvement—all of which are available at www.simplifypriorauth.ca. The SPA has also been instrumental in fostering an electronic, made-in-Canada prior-authorization solution that will continue supporting opportunities and drive prior-authorization improvements.[4]

Opportunities to improve prior authorization

Unfortunately, there haven't been significant changes or reform to Canadian private drug plan prior-authorization programs. "Plan advisors and plan sponsors have been largely unaware of prior authorization's growth, the complexity of the process, as well as the high administrative burden of prior authorization on all stakeholders," said Denise Balch, project manager, Simplify Prior Authorization and president, Connex Health Consulting. "The existing prior-authorization process can result in delayed access to medications plan members need, which can result in higher presenteeism and delays in return to work."

Assessing the value of prior authorization

It can be beneficial to assess drug programs to determine whether they provide value. Plan sponsors could request the following information to assess the value and effectiveness of their PA program:

- ☐ What percentage of PAs are approved versus declined with respect to the cost of PA processing and plan savings?
- ☐ What percentage of PAs are approved versus declined for initial PA and PA renewals?
- ☐ What's the impact of PA requirements on individual plan members or conditions?
- ☐ What's the impact of PA processes and timelines on plan members' health and potential disability?
- ☐ What are the cost and health implications of requiring patients to fail older treatment options first before they're approved for a more clinically efficacious treatment?
- ☐ How long is the PA review timeline for plan members to begin treatment? Are there potential health impacts for delayed access?
- ☐ If the drug a plan member needs is NOT covered, what are the alternatives? Will the payer recommend options to the patient and help them seek coverage?

Electronic prior authorization (ePA) in Canada

According to Balch, a flexible and affordable electronic prior-authorization (ePA) technology solution that recognizes the Canadian market's unique requirements wasn't available until relatively recently. Experts from the Simplify Prior Authorization[4] ePA working group explored the market and identified a provider with a technology solution that delivers ePA, while providing benefits at critical stages of the prior-authorization process. "But because of competing priorities—and the commitment of time, resources and technology infrastructure to integrate ePA—non-payer stakeholders will have to be patient during the adoption process because complete payer integration will take some time," said Balch.

> Plans that deny coverage based on seemingly arbitrary criteria are at greater risk of unintentionally imposing a discriminatory effect on a plan member. "Best practices should involve clearly documented and reasoned criteria for authorizations—and standardization, to the extent possible, can be a helpful component of the process."
>
> MITCH FRAZER
> managing partner, Mintz LLP Toronto

> Unfortunately, there haven't been significant changes or reform to Canadian private drug plan prior-authorization programs.
>
> DENISE BALCH
> project manager, Simplify Prior Authorization and president, Connex Health Consulting

123RF/ MOUNTAINBROTHERS

Prior-authorization improvement could reduce paperwork and streamline communication between providers, pharmacists and payers, said Sist.

Stakeholders have identified potential opportunities to improve current PA processes:

i. Introduce ePA with functionality for online approvals, declines and visibility of the PA status for tracking purposes.

ii. Set up an expedited customer contact and review process for patients who need lifesaving medications.

iii. Allow patient support programs or reimbursement navigators to inquire or follow up on a patient's behalf—this can prevent a sick patient or their caregiver from having to participate in every step.

iv. Create a clear, expedited process for complex issues and escalations to ensure a timely response.

v. Automate PA renewals for patients who are stable on their current treatment—this can reduce administrative burden for all stakeholders (i.e., patients, doctors, insurers and patient-support programs).

vi. Payers could reconsider PA on drugs that have been on the market for a while (i.e., a drug that has been available for a while that has a high success rate of PA approval due to appropriate use).

vii. Payers could proactively share PA eligibility criteria so that PA forms aren't submitted for patients who wouldn't meet the criteria.

viii. Ensure there's an equitable, fair, transparent, documented process for appeals on declined claims, including what additional evidence would be considered.

ix. Publish expected service levels for processing PA requests.

9. External drug plan managers

Some plan sponsors choose non-traditional third-party drug plan managers to oversee their formularies or prior-authorization processes. Instead of having their insurer manage health benefits, they choose an independent expert. "Potential problems may arise if the formulary management and/or PA programs operate in silos from one another," noted Lathia.

In addition, there may be drug plan management challenges because an external manager may not have visibility of important information, such as:

a. plan member claims history;

b. plan coverage documents;

c. plan's financial risk;

d. payer-negotiated product listing agreement (if the primary payer negotiated a discounted price for a drug with a pharmaceutical manufacturer, the plan sponsor won't benefit from this lower price if they use an external drug plan manager).

Potential benefits:	Potential challenges:
• independent drug plan management expertise • improved plan member support (i.e., assisting members in navigating alternative funding for declined claims) • portability when moving between payers	• customer service disruption (insurer call centres and secure websites can be complicated when an external payer is involved) • delays and confusion because PA requests go to the payer instead of external provider • insurer and plan sponsor have responsibility for plan risk and liability of coverage decisions made by an external manager

123RF/VLADYSTOCK

To assess the value of an external manager, plan sponsors should compare the cost, approval rate and plan member experience with that of their insurer's.

> "Potential problems may arise if the formulary management and/or PA programs operate in silos from one another."
>
> Nina Lathia
> health economics consultant and founder and CEO, Healthcare Decision Making

10. Managed formulary alternatives

Restricting drug access isn't the only way to manage drug plan cost. It's important for plan sponsors to maximize these plan designs first. Some examples of cost-saving plan designs include:

- generic drug plans that can generate savings by requiring lower-cost generic alternatives;
- biosimilar policies or PLAs for brands with available biosimilars can generate savings due to the availability of lower-cost biosimilar alternatives for high-cost biologic drugs;
- coinsurance that shares claim costs with plan members, encouraging them to be cost-conscious consumers;
- payers that sign PLAs with pharmaceutical companies to reduce drug prices, which can potentially generate savings for plan sponsors and members;
- preferred pharmacy networks that encourage use of lower-cost providers to reduce drug-acquisition cost;
- plan designs that require chronic medications to be filled at 90-day intervals to save on monthly dispensing-fee costs.

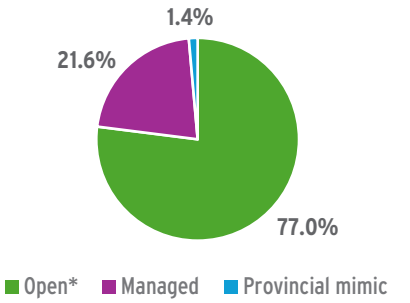
123RF/STOCKING

Private drug plan snapshot

A variety of plan designs are used to manage drug plan costs. Analysis shows that 21.6% of plan members with private plans have a managed formulary and over 90% have a generic drug plan, split between mandatory and voluntary generic.

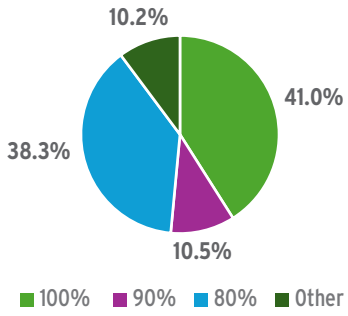
A large percentage of members have 100% or 80% coverage for their drug claims costs.

Formularies

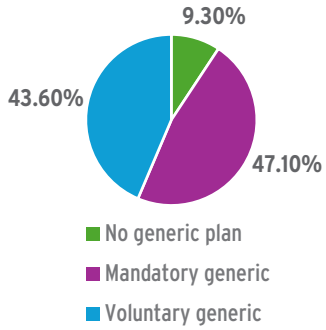


*Open formularies generally have a prior-authorization program.

Coinsurance



Generic drug plans



Based on % of lives (2023)

Source: CloudAdvisors

11. Plan sponsor checklist

- ☐ Assess potential legal liability of payer-declined claims. How does an employer's drug plan align with the payer's contract? Is there potential for discrimination?
- ☐ Ensure the payer's drug plan management philosophy aligns with the plan sponsor's.
- ☐ How does the payer's drug review committee assess new drugs? (i.e., clinical effectiveness, cost effectiveness and financial impact)
- ☐ How long does the payer take to list drugs? Could delays impact plan members' health?
- ☐ Does the payer rely on public drug plan drug reviews or do they assess cost effectiveness from a private-payer perspective?
- ☐ Does the payer publish their drug plan review timelines, assessments, outcomes and rationale for coverage recommendations?
- ☐ Are prior-authorization processes transparent, objective, timely and aligned with formulary management?

123RF/JOHN6863373

REFERENCES

1. Data provided by Medavie Blue Cross
2. https://www.benefitscanada.com/wp-content/uploads/sites/7/2023/09/BCHS-Report-2023-0925-ENG.pdf
3. Data provided by Innovative Medicines Canada
4. www.simplifypriorauth.ca

SPONSORS

abbvie

ALEXION
AstraZeneca Rare Disease

AMGEN

cencora
Innomar Strategies

INNOVATIVE MEDICINES CANADA

janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

MEDAVIE BLUE CROSS™

Roche

VERTEX

DATA SPONSOR:

cloud Advisors