



» Getting drug plan costs under control with a managed drug formulary

With expensive new drugs continually coming to market, all payors (as well as plan sponsors) are looking for ways to dial down the fiscal pressure on drug plans. While there are many means to contain drug costs, at GSC we're firm believers in responsible management that ensures plan members get access to the most appropriate therapy for their condition. We do this through managed formularies, an approach that can help control your drug spend and ensure plan sustainability.

This isn't a new concept – managed formularies have been around since the early 1990s when so-called "blockbuster" drugs arrived on the scene. Back then we quaintly thought a drug that cost a dollar a day would bankrupt a plan! Plan sponsors reacted by freezing their formularies, but that meant their plan members weren't able to benefit from the new drugs, many of which offered advanced treatment options.

GSC has always operated with a philosophy of balancing value for plan sponsors with offering uninterrupted access to treatment to plan members. In that spirit we developed a managed drug formulary called the Green Shield Canada Conditional Drug Formulary[®]. Introduced in 1996, it was the first of its kind in Canada – designed to protect a drug plan from expensive drugs that were not proven to treat medical conditions more effectively than similar, less expensive drugs. Instead of a free-for-all environment or no access for anyone, we want to ensure the **right drug, for the right person, at the right time.**

The Conditional Drug Formulary: still a good idea in 2018

Now 22 years later, the Conditional Drug Formulary is more relevant than ever. As we all know, drug costs continue to go up and up, yet the vast majority of GSC plan sponsors have open drug plans – only slightly over 20 per cent have the Conditional Drug Formulary. Why is that? Often it's because plan sponsors have misapprehensions about managed formularies such as:

- Many drugs aren't covered
- There are delays and unnecessary restrictions in drug access
- Plan members can't easily determine what drugs are covered
- Plan members will have a poor experience
- A fear of the unknown

More popular than you might think...

Managed formularies are actually a very common type of drug plan, at least in the public sphere. All the provincial drug plans are based on managed formularies to one degree or another. And since these plans always cover residents age 65 and over, everyone will be covered by a managed formulary when they get older.

In the U.S., prescription drug plans all follow managed formularies. While they differ on levels of coverage, they are all much more highly managed than any private drug plans here in Canada.

Open formulary versus the Conditional Drug Formulary

At GSC, all newly approved drugs on the market are first evaluated by a committee of pharmacy experts to determine whether the drug will be included on the formulary for reimbursement (subject to conditions or limitations) based on clinical effectiveness, safety, and value to plan sponsors and plan members.

Open formulary

Under an open formulary, all newly approved drugs are added and eligible for reimbursement, regardless of their cost or whether the drug provides any additional value over existing therapies or not. Most drugs are added as full benefits, but there are a limited number of conditional drugs (also called individual consideration drugs). These drugs are mainly specialty drugs and require prior authorization on **both** open and managed formularies.

Conditional Drug Formulary

Under the Conditional Drug Formulary, all approved drugs are assigned to one of three categories:

- **Full benefit/approved:** The drug is eligible for reimbursement and no special process is required. As long as there's a prescription, it will be filled at the pharmacy.
- **Individual consideration:** Approval for the drug is granted if the plan member meets certain conditions. A physician must submit a special request form demonstrating the conditions are met. Each request is reviewed by an in-house consultant. The list of individual consideration drugs under the Conditional Drug Formulary is slightly more extensive (12 per cent of all drugs) compared to the open formulary (four per cent) as it goes beyond high-cost specialty drugs to also include chronic disease drugs.
- **Non-benefit/denied:** The drug is not eligible for reimbursement. The plan member can try an alternative treatment option or pay for the denied drug out of pocket.

Things to keep in mind

- Approved drugs are full benefits both on the open formulary **and** the Conditional Drug Formulary.
- Many individual consideration drugs are the same under both formularies as well.
- Drugs that are non-benefits on the Conditional Drug Formulary are approved as full benefits on the open formulary without any restrictions or limitations.
- With both formularies there are opportunities for add-on cost management strategies such as mandatory generic substitution, maximum allowable cost pricing, etc.

Let's take a closer look...

"Managed" doesn't mean that a lot of drugs aren't covered. In fact, the majority of drugs – 86 per cent – are still full benefits on the Conditional Drug Formulary. Only a small number (12 per cent versus four per cent in an open formulary) are considered conditional, and an even smaller number are considered non-benefits (two per cent).

We add criteria around specific drugs to ensure people who really need access to that drug will get it. For instance, when a drug is categorized conditional, it can be because we want patients to try a cost-effective drug before we'll reimburse the more expensive product. As well, we don't cover drugs that perhaps aren't all that expensive but don't offer an advantage to the plan member or can be used in ways that don't align with the intent of the plan (e.g., Botox for wrinkles). These require prior authorization because we want to ensure patients are following the appropriate treatment pathway based on clinical guidelines and evidence. In many ways, the Conditional Drug Formulary simply ensures prescribing adheres to clinical treatment guidelines, which is equally important from a safety and a cost effectiveness perspective.

We make it easy to find out what drugs are covered

Plan members who have registered for GSC's Online Services can easily find out the category of the drug they're prescribed by using the "Is My Drug Covered" tool. (A similar tool is included on GSC's mobile app as well.) And if the drug requires authorization, the plan member will be able to print the necessary form for their physician to complete.

Categorizing a drug as a non-benefit isn't intended to deny treatment for plan members. Many of the non-benefit drugs, for example, are "me-too drugs" that offer no advantages over existing options but often cost much more. They don't typically offer better clinical treatment, but they're marketed as providing an improvement in efficacy, a differing safety profile, or as effective in patients who are resistant to the original drug, etc. Be assured that plan members will always have options under the plan; they can consult their physician regarding alternatives or pay the full drug cost if they are inclined to use only the drug prescribed.

While it's understandable to be cautious about implementing the Conditional Drug Formulary instead of an open formulary, it's not really such an enormous change for plan members. Remember, for 86 per cent of drugs, there will be no change in coverage; only a small subset of costlier drugs will be impacted. As long as plan members are part of the conversation and receive comprehensive information about the change, they shouldn't find it confusing or restrictive.

A changing environment...

Over the years, private drug plans have been accused of not managing costs properly and being overly generous by covering too many drugs. This criticism is currently the impetus for the discussion around national pharmacare.

At GSC, we like to be as transparent as possible about the state of our industry – we do feel that drug plan management in the private insurance industry is outdated and needs to evolve. We still hear about plan sponsors introducing a dollar cap on an open plan where, for long-term cost management, a managed formulary would be a more thoughtful and balanced choice. With the Conditional Drug Formulary, our goal is simply to offer value to plan sponsors. We are not trying to limit treatment options or deny access, but are trying to drive decisions toward more cost-effective products while still maintaining access to necessary treatment.

One thing is certain: high-cost therapies will continue to drive up future benefit costs. So, if you're thinking about implementing a managed formulary, you'll want to get on board as early as possible as savings are accrued over the long run... and there will definitely be savings.

The Conditional Drug Formulary = SMARTspend

If you're going to offer a benefits plan, then be sure you're getting value out of the money you spend so that you can continue to provide benefits for the long term. When GSC set out to assemble all our cost-management policies, strategies, and initiatives under the SMARTspend banner, the key motivating factor was to offer value. And since the overriding goal of the Conditional Drug Formulary is to provide value, we've included it in our new SMARTspend plan design.

You'll be hearing a whole lot more about SMARTspend and the plan design in the coming weeks, stay tuned!

Not ready to commit to the Conditional Drug Formulary?

We will soon have another option for you – one that falls somewhere in the space between the Conditional Drug Formulary and an open formulary.

Our new approach to formulary management will enable automatic approval of drugs based on a plan member's claims history for a select list of drug benefits.

This process is one of several strategies used today as part of our Conditional Drug Formulary but will soon be available on its own for those who are contemplating moving in the direction of a managed formulary but are not quite ready to fully implement the Conditional Drug Formulary. The automatic approval happens in real time while the plan member is at the pharmacy counter. They will be unaware of the prior authorization process taking place, making it a seamless experience for those who are approved.

We'll be introducing this new managed formulary early in 2019, so watch out for more details soon.



BEHIND THE COUNTER



Our feature in this issue of *Follow the Script* describes the value provided to plan sponsors through the GSC Conditional Drug Formulary. To shed more light on the roles of pharmacists, insurers, and doctors in supporting the formulary, we talk with Ned Pojskic, GSC's leader, pharmacy & health provider relations. (He's not a pharmacist, only a PhD in pharmaceutical policy... but we'll still talk to him on this topic.)

Follow the Script: Ned, since we've been teasing this concept of SMARTspend through podcasts and the Inside Story®, would you suggest that the Conditional Drug Formulary was SMARTspend even before there was a SMARTspend?

Ned: Yes, I think we can say that. Like the other benefits under SMARTspend, the Conditional Drug Formulary adds rigour to ensure the drugs we reimburse are adding value. It's not so much what we pay or don't pay – it's not a binary thing. The idea is to enforce prescribing according to clinical guidelines. We want to ensure that prescribing will follow the guidelines instead of being ad hoc or driven purely by physician preference without clinical rationale.

FtS: What's driving the production of drugs that we're saying don't add value?

Ned: We can look at that question in a couple of different ways. Drugs will be produced and added to the market for business reasons that aren't always necessarily commensurate with a level of improvement to patient care. The typical scenario is one where a drug loses its exclusivity, then the drug manufacturer revamps it ever so slightly through small changes – making it faster absorbing or longer duration, for example. This doesn't fundamentally change the active ingredient of the drug, so does it add value to a purchaser? But some of these changes can be argued to be valuable in their own right. For example, if I have to take a drug once a day versus twice a day, then that is clear value. People are much more likely to take a drug once a day than twice a day – we know that from research – this enhances adherence, leading to better health outcomes. The issue we as a pharmacy benefit manager and carrier struggle with – indeed, every drug plan manager loses sleep over this one – is when a drug improves outcomes by 10 per cent, yet it's three times more expensive. So this is the question: Is that 10 per cent worth the extra three times the price? Then you get into the more fundamental question – how do you attach a price to health and quality of life?

FtS: Let's talk about that 10 per cent thing. It's probably not the difference between life and death. Is there any other product where we would say, "OK, if you improve that product by 10 per cent, then I'll pay three times more?" That sounds like lunacy.

Ned: It does, but when you break it down to a personal level... this is a struggle because we're using hard quantitative science to measure an experience that is difficult to quantify in numbers. For a child who can breathe 10 per cent more – that's significant for them.

FtS: Then why doesn't the drug cost 10 per cent more?

Ned: That's the million-dollar, or sometimes multi-million-dollar question. Pharmaceutical companies will argue that their drugs are priced based on previous research failure, not necessarily on success – 10 new agents will fail in development for one to work. And someone has to pay for the failure. They say that because of the complexity of the human makeup, they have to use trial and error – by definition things will fail. Is it fair that their pricing is three times more? We argue "no," they argue "yes" – because of that financial risk.

FtS: Where does the Conditional Drug Formulary come in to that debate?

Ned: The Conditional Drug Formulary is certainly more rigorous than simply saying we'll pay for anything, but it's not so rigorous as to make unsubstantiated decisions around coverage. Sometimes you'll see managed formularies that take a very bold stand and say: "We will not pay for 30 per cent of new drugs coming to market because we don't see value." We think that's likely too aggressive, and it doesn't actually serve anybody well. What we do is take a more nuanced approach; the Conditional Drug Formulary simply adds step therapy to the process. We say: "You're going to start on a lower-cost drug, and if we see that it's not working for you – if you're not achieving health outcomes – then you move on to the higher-cost one." We might add the new, more expensive drug as a fifth-line treatment – a patient has to fail four treatments before getting it, but at the very least, if there's the one per cent of people who really need it, they'll have access to it.

FtS: I assume we get pushback from patients, doctors, and manufacturers for our decisions?

Ned: The pushback on the Conditional Drug Formulary, or really any managed formulary, comes down to the question: Does an insurance company have a right to intervene in patient-care decisions? This is a philosophical question that many of our clients answer with "no." They say: "Do not intervene in the doctor and patient relationship. You don't know what they know." Other clients feel there's too much evidence that says physician prescribing is not optimal or rational, and somebody needs to step in and intervene. Who else is going to do that other than an insurance company? So when we get this pushback from a physician – "how dare you intervene?" – we say: "Just tell us why we might be wrong. Tell us why you think the five-times-more-expensive drug is more appropriate than the first-line treatment option for this patient. We're astute, rational people, so we may agree that this makes sense."

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FtS: Is it fair to say that in the majority of these cases, there is no sound rationale for physician prescribing patterns?

Ned: I would say yes. The vast majority of cases, when that physician response comes in, it doesn't even come in with a rationale. They're saying this is my preference as a physician; abide by my preference. GSC says we need to have a rational conversation; preference doesn't matter if it's not supported by evidence.

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FtS: So we've talked about insurance companies and physicians, but what's the pharmacist's role in this equation? They're supposed to be the experts on drugs and presumably value.

Ned: That's a really good question. You think about the process of getting a drug: it's prescribed then there's this last line of defence – the pharmacist – before it's handed over to a patient. So could pharmacists act as that additional check? They assess the appropriateness of drug therapy but that's a pretty low bar; it's essentially a test of whether it will harm you. Most of our health care system adjudicates on the basis of harm; there's very little consideration of value. Regulatory colleges judge health professionals on the basis of "did they cause harm?", not whether they actually improved a patient's health. So pharmacists look at the basic information about the prescription: is it contra-indicated... is it appropriate for the condition... is the dose too high... that kind of thing. But they don't consistently consider details like, "You've been on this therapy for this duration of time, I wonder if this is still appropriate for you or is there a better agent to treat what you have?" That type of clinically-intensive work occurs in certain high functioning pharmacies, but certainly not for the vast majority of pharmacies out there.

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FtS: Would a community pharmacist have the information about the patient to ask those questions?

Ned: Often no; in their defence, they don't have the full clinical history, and if they did have that, they may not see the nuances in that history that may warrant the decision the prescriber made. So it's difficult for pharmacists in the community to really delve deeply into a prescribing decision without going through an extensive patient interview. Provincial governments have recognized the value of the pharmacist in that role, and that's why they designed programs like MedsCheck. The idea was, let's periodically sit down with you – the patient – talk through what you've been prescribed, what medication you could perhaps stop taking, what should be optimized, etc. MedsCheck was designed to act as an additional check, but it never actually ended up serving that purpose because few practitioners really wanted to engage in that level of clinical work. To go back to the question about the role of the pharmacist in assessing efficacy and value, it's not happening uniformly right now but needs to happen more consistently.

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FtS: Doesn't a pharmacist ideally have a more balanced view of both efficacy and how much a drug costs? In an ideal world wouldn't it make people feel better if pharmacists lived up to being the experts on drugs that they're supposed to be?

Ned: If you think about it, some pharmacists are performing that role. Except they're not necessarily in the community pharmacy – they work for the carrier. Here, it's our GSC pharmacists that do that work.

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FtS: Thanks, Ned, for your insightful thoughts on this topic.

DRUG REVIEW AT GSC...

To give you an idea of what drugs might impact your benefits plan next, every quarter *Follow the Script* highlights some of the drugs recently reviewed by GSC's Pharmacy and Therapeutic (P&T) Committee.

GSC CLASSIFICATION ¹	NEW DRUG ²	GENERAL INFORMATION	COST ³	COVERAGE DETAILS ⁴
NEUTROPENIA				
Biologic; Specialty (Tier 5)	Lapelga™ (pegfilgrastim)	Chemotherapy is used to treat many types of cancers but can also result in significant side-effects. Myelosuppression is a common complication characterized by a reduction in bone marrow activity leading to decreased levels of certain blood cells. Neutrophils are a type of white blood cell that helps the body fight infections. When cancer treatment causes low levels of neutrophils it is referred to as <i>neutropenia</i> . When neutropenia is accompanied by a fever (a sign of infection), it is not only a serious life-threatening complication but can also result in treatment delays or dose reductions which negatively impact patient outcomes. In these situations, timely assessment and treatment is often required to prevent further serious complications. In some cases, treatments with granulocyte-colony stimulating factors (G-CSF), also known as myeloid growth factors, can reduce infectious complications by increasing levels of neutrophils in the body. ^{5,6,7}	<p>\$\$\$\$</p> <p>Approximately \$15,029 per year ⁸</p> <p>Represents a 25% discount compared to the originator biologic Neulasta.</p>	<p>→ Full benefit</p> <p>Note: Neulasta will be allowed only in exceptional circumstances in accordance with our Biosimilars Policy.</p>

GSC CLASSIFICATION ¹	NEW DRUG ²	GENERAL INFORMATION	COST ³	COVERAGE DETAILS ⁴
NEUTROPENIA (CONTINUED)				
<p>Biologic; Specialty (Tier 5)</p>	<p>Lapelga™ (pegfilgrastim)</p>	<p>Lapelga represents the first pegfilgrastim biosimilar to be approved by Health Canada based on demonstrated biosimilarity to the reference biologic Neulasta®. It was approved by Health Canada to decrease incidence of infection, as manifested by neutropenia accompanied by a fever (also known as febrile neutropenia), in patients with non-myeloid malignancies (cancers that do not involve the myeloid cells) receiving myelosuppressive cancer drugs. Just like Neulasta, Lapelga works by increasing the production of the neutrophils to reduce susceptibility to infections, but it offers a more affordable option for patients when compared to Neulasta.</p> <p>Additionally, compared to Grastofil® (filgrastim), which was the first G-CSF biosimilar product to be approved, Lapelga is a form of filgrastim that provides increased stability and a longer duration of action in the body leading to less frequent injections. Lapelga is administered as a single subcutaneous injection (injected into the fatty tissue just under the skin) once per cycle of chemotherapy.</p> <p>Since the launch of GSC's Biosimilars Policy in 2016, GSC has approved six biosimilars for our formularies and, as the portfolio of biosimilars continues to grow, the value and cost-saving opportunities are becoming more apparent both now and for the future.</p>	<p>\$\$\$\$</p> <p>Approximately \$15,029 per year ⁸</p> <p>Represents a 25% discount compared to the originator biologic Neulasta.</p>	<p>→ Full benefit</p> <p>Note: Neulasta will be allowed only in exceptional circumstances in accordance with our Biosimilars Policy.</p>

Notes:

¹ Traditional generally refers to small molecule compounds derived from chemical synthesis and also includes drugs not listed in Schedule D of the Food and Drugs Act; Biologic refers to drugs produced through biotechnology and listed in Schedule D of the Food and Drugs Act; High-cost refers to drugs subject to GSC's High Cost Drug Policies; Specialty (Tier 5) refers to drugs with an expected annual treatment cost of \$10,000 or more (certain drugs approaching the threshold may also be considered if clinically warranted).

² Brand (generic)

³ Based on manufacturer list price, does not reflect pharmacy markup and dispensing fee. \$ <1,000; \$\$ 1,000–4,999; \$\$\$ 5,000–9,999; \$\$\$\$ 10,000–49,999; \$\$\$\$\$ ≥50,000

⁴ Applicable to all formularies unless otherwise noted. PPN refers to GSC's preferred pharmacy network program.

⁵ Neutropenia, Cancer.Net, <https://www.cancer.net/>

⁶ Febrile Neutropenia, BC Cancer, <http://www.bccancer.bc.ca/>

⁷ Febrile Neutropenia, UpToDate, <https://www.uptodate.com/>

⁸ Based on a 21-day chemotherapy cycle and an average of eight cycles