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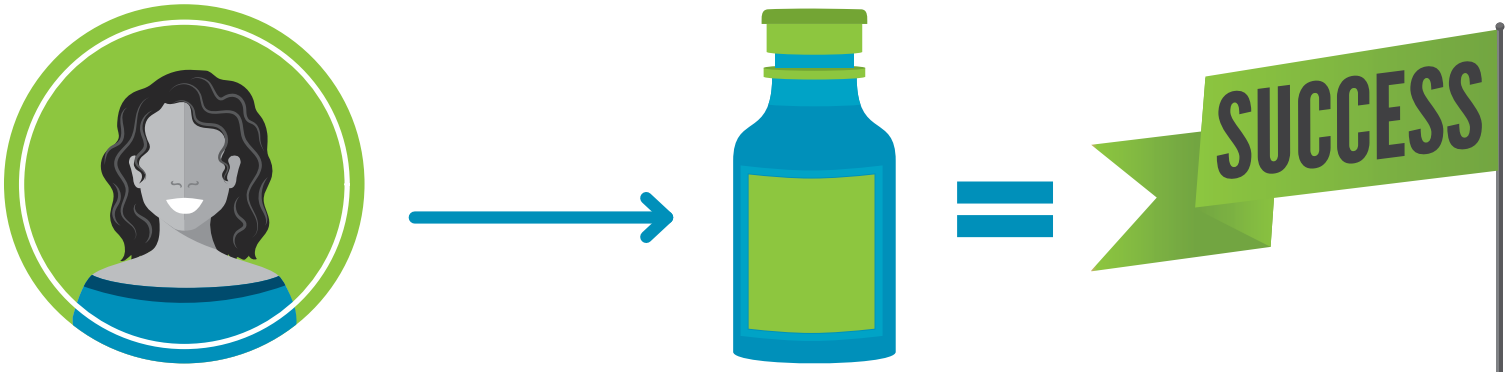
WINTER 2018



Green Shield Canada's Biosimilar Transition Program completes a successful pilot

Earlier this year Green Shield Canada (GSC) introduced our Biosimilar Transition Program, which we piloted with three of our plan sponsors through the summer and into the fall of 2018. The pilot is now complete, and following its success, we're pleased to offer this innovative program to all GSC plan sponsors. In the meantime, here's an overview of the program and the highlights of the pilot results.

Safely transitioning patients to a biosimilar

As you may recall, in 2016, GSC started listing biosimilars as preferred products under our formularies and covering the originator products only in exceptional circumstances for patients newly starting biologic therapy.

After introducing our biosimilar standard, GSC monitored and investigated the emerging scientific evidence examining the safety and efficacy of transitioning from an originator biologic product to the biosimilar counterpart. We also consulted with the Arthritis Consumer Experts, a leading national, patient-led organization that provides evidence-based education in Canada. Since all evidence pointed to patients safely transitioning from an originator biologic to a biosimilar product with no loss of clinical benefit and no compromise in safety, we launched GSC's Biosimilar Transition Program and commenced the pilot.

Let's review: biologics versus biosimilars…

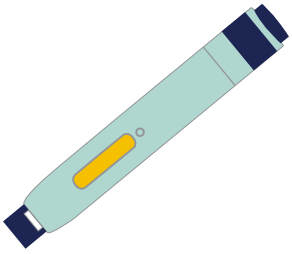
Biologic drugs provide treatment options for serious or rare illnesses where no effective treatments were previously available, such as cancer, rheumatoid arthritis, multiple sclerosis, and diabetes. While drugs in this class are generally very effective in treating these illnesses, they can be extremely expensive.

A **biosimilar** is a product structurally **highly similar** to a specific originator biologic product that is produced after the patent of the originator drug expires. Biosimilars can achieve the same positive health outcomes as originator biologics, but at significantly lower costs.

What drugs and conditions?

The Biosimilar Transition Program currently focuses on Remicade® and Enbrel® for these rheumatic conditions:

REMICADE	ENBREL
→ Rheumatoid arthritis	→ Rheumatoid arthritis
→ Ankylosing spondylitis	→ Ankylosing spondylitis
→ Psoriatic arthritis	



Note that as the evidence on transitioning to biosimilars grows, more indications for the existing biosimilars are approved, and new biosimilars enter the market, the number of drugs and indications eligible for the GSC program will grow.

Snapshot of the pilot

Eligible plan members were identified for the three GSC plan sponsors that participated in the pilot. Of these, 41 per cent of plan members transitioned from the originator biologic (Remicade or Enbrel) to a biosimilar product, and 26 per cent chose to remain on the originator at the reimbursement level of the biosimilar. This means that 67 per cent of participants were reimbursed the cost of the biosimilar resulting in significant savings. Our analysis showed an average savings of $8,500 per member per year for the population participating in the pilot.

Nine per cent of plan members were approved to continue on the originator biologic after providing valid clinical justification. Independently of this transition program, three per cent changed treatment to an entirely different drug. At the time of publication of this article, 21 per cent had not yet submitted a claim, so we're unable to determine status of their transition.

The plan member experience

One of the goals of the pilot was to ensure that the processes we have in place result in an optimal plan member experience. We initially launched the pilot with a 60-day transition period, but changed it to 90 days based on feedback from participating plan sponsors. This was an important learning that resulted in a change to the program going forward.

To provide a strong support system to help plan members with the transition, GSC has partnered with HealthForward, the leading payer service provider for Medication Management in Canada focused on optimizing patient health outcomes and access to therapy. HealthForward's dedicated team of care-coordinator nurses follows a detailed case management process to provide plan members with the assistance they need.

First step… a letter from GSC

Plan members taking Remicade or Enbrel for one of the targeted conditions were sent a letter explaining the program, the evidence for transitioning, and next steps. The letter outlined the two available options: (1) to go ahead with a one-time transition to the biosimilar after discussing it with their doctor; or (2) to continue treatment with the originator biologic and pay the difference in cost between the two products. Contact information for HealthForward was also included in the letter.

The reduction in a plan member's claim reimbursement began 60 days after the date of the letter. Claims weren't denied, we simply based reimbursement on the biosimilar price regardless of the drug submitted on the claim.

HealthForward care-coordinator nurses ensure there are regular touchpoints (beginning when the plan member first contacts HealthForward, one month later, three months later, and six months later) to check in with the plan member, address any issues, and answer questions. There is also a dedicated phone line that plan members can call at any point during their transition should they need additional support.

Both GSC and HealthForward have considerable experience in managing initiatives such as the Biosimilar Transition Program, and we didn't encounter any unexpected questions or concerns during the pilot. Here are some highlights from the calls:

- Most plan members understood the change being made to their plan and were receptive.
- Some proactive plan members had already discussed transitioning to a biosimilar before receiving the letter.
- Questions included: reasons for the change, amount covered under the plan, cost difference between the originator and the biosimilar, efficacy of the biosimilar, and next steps.
- Some plan members had questions about the efficacy of the biosimilar and their potential response to it compared with their experience on the originator product. Their concerns were satisfactorily addressed by the HealthForward care-coordinator nurses.
- A number of plan members expressed appreciation for the support provided by the care-coordinator nurses.

What's next?

With the completion of the pilot program, GSC is now opening up the program to any plan sponsor who wishes to add it to their plan. We strongly encourage you to speak to your GSC account team about opting in to the Biosimilar Transition Program. Note that the program currently applies only to situations where GSC is the primary payor (i.e., not for coordination of benefits claims) and is not available for residents of Quebec (where GSC has to provide the same level of coverage as RAMQ).

Want some background on this topic?

You can find information from GSC about biosimilars (a.k.a. subsequent-entry biologics or SEBs) here:

- *Follow the Script*, summer 2016
- *The Inside Story*, December 2016
- GSC Update, March 2018
- "And now for something completely indifferent..." podcast, episode 7

BEHIND THE COUNTER

Looking back… and looking forward

It's been some time since we brought our GSC pharmacy strategy team together to talk about the issues they see as key in the area of drugs or pharmacy. With this end-of-the-year issue of *Follow the Script*, we asked them to look back at 2018 and forward to 2019. We're happy to welcome Marilyn Jung, pharmacy strategy specialist, Leila Mandlsohn, pharmacy strategy consultant, and Ned Pojskic, leader, pharmacy and health provider relations.

Follow the Script: This seemed to be a busy year in your space. Let's start with pharmacy – what was Canadian pharmacy concerned about and talking about in 2018?

Leila: A lot of what's being talked about in the pharmacy community has to do with the political environment and how that impacts the business of pharmacy overall. The focus in particular has been on the reimbursement side, not only on the core activities, like dispensing, but also the expanded scope of practice.

Ned: Pharmacy continues to have concerns about downward pressure on their reimbursement from governments. Not so much from private payors – I don't think anyone has changed their framework on the private payor side. But what does concern pharmacists is how generic and brand-drug prices are coming down. Even if the overall framework doesn't change, pharmacies' revenue is in part determined by the price of the drug. So, they're being reimbursed less because a 10 per cent markup on $50 is a lot less than 10 per cent on $100.

FtS: And drug prices are coming down because…?

Ned: I think generic price reforms have had a substantial impact. And that means GSC plan sponsors are paying less for those drugs, but keep in mind that total drug spend doesn't go down, it just gets replaced by something else – usually an expensive new therapy or treatment.

FtS: So that's what's happening – we're getting the savings over on one side, which is good news. But expensive new drugs are coming in on the other side, so you have to use the money to pay for them.

Marilyn: The new expensive drugs coming to market are often specialty drugs, and the pharmacies feeling the pressure the most are those that don't generally handle specialty drugs.

FtS: What is our take on the year in new drugs? Was it as dramatic as we expected? And what came in this year and what's coming down the pipeline in the next couple of years?

Ned: An interesting one is Spinraza™ for spinal muscular atrophy. For the first year it costs over $700,000, then over $350,000 a year after that for maintenance. That was a huge unexpected hit to private payors this year. But there aren't any alternative treatments available for these patients.

FtS: Why was it unexpected?

Leila: Spinal muscular atrophy is a rare condition, but the prevalence in our population turned out to be higher than we had estimated. And Spinraza is injected into the spinal canal. Often sedation and access to ultrasound are required, particularly in younger patients, to make sure it is administered appropriately – as a result it has to be done in a hospital,

Ned: This sort of issue is going to continue to come up. We're seeing highly complex drugs that require some sort of specialized care for administration, like Spinraza, yet the cost of the drugs is not being covered by hospital budgets. The line between what should be paid for by hospital budgets and what rightfully belongs on private plans continues to get blurred.

FtS: Why is that?

Leila: These are not treatments used in the acute-care setting for acutely ill patients admitted to hospital. Instead, these are drugs that generally treat some form of chronic condition for patients in the community whose only reason for visiting the hospital is to have the drug administered. Gene therapy is another example that could impact the private payor spend: is it a drug or not? There's a whole new world coming to market, and these treatments don't fit nicely into the traditional acute-versus-chronic or public-versus-private coverage buckets.

FtS: Tell us about gene therapy.

Ned: It's a new category of ground-breaking treatments, and the first one has already been approved. There are others right around the corner, including one to treat spinal muscular atrophy. Gene therapy has the potential to be a game-changer in terms of improving health outcomes, but the treatment is incredibly expensive. And it could be argued that it's more of a procedure than a drug, so who pays?

Marilyn: It's all new to us, we're learning as we go along.

Leila: The public payor side struggles with this too – an increasing availability of drugs and procedures that don't fit perfectly into existing frameworks for approval and evaluation. It happened with biosimilars, and it happened with subsequent-entry non-biologic complex drugs. CADTH [Canadian Agency for Drugs and Technologies in Health] has had to create new frameworks of evaluation for these new types of drugs and treatments that are coming to market.

Marilyn: Given its unique aspects, CADTH has indicated it will be reviewing gene therapy under its medical devices stream and not through one of its drug review streams – even though Health Canada has assigned it a DIN. But at the end of the day, you're taking someone's blood, sending it to a lab, injecting something so it modifies the cell's DNA, then putting it back into the patient's body. Gene therapy could be used for almost anything – any type of genetic disease. And there's a lot of development in this space.

Ned: So gene therapy is going to be the next conversation in our industry. And here's my prediction for that: carriers and pharmacy benefit managers will struggle to find a way to pay for these treatments partly because most are not preparing for it adequately right now. When I've talked to pharmaceutical companies on this, they're saying that no one is even thinking about this, yet the first gene therapy treatment has already been approved in Canada.

FtS: OK, let's change topics and talk about biosimilars. Apart from what GSC is doing, have there been any improvements in the uptake of biosimilars?

Ned: The public plans are starting to get on board. The pCPA [pan-Canadian Pharmaceutical Alliance] has released its Biologics Policy Directions which reaffirms its commitment to biosimilars.

Leila: Something else that we've seen is that not only are biosimilars bringing in savings, but also those products are forcing down the price of the new originators coming to market. They know they have to come in with a competitive price because they have to compete with biosimilars. So that's good.

Marilyn: The recent announcement by Biosimilars Canada around the patient support program is also a good sign – they're consolidating so that there is one vendor providing one point of contact for all biosimilars. And the ORA [Ontario Rheumatology Association] has a good position statement supporting biosimilars; these specialists are coming down in favour of transitioning, so momentum is growing.

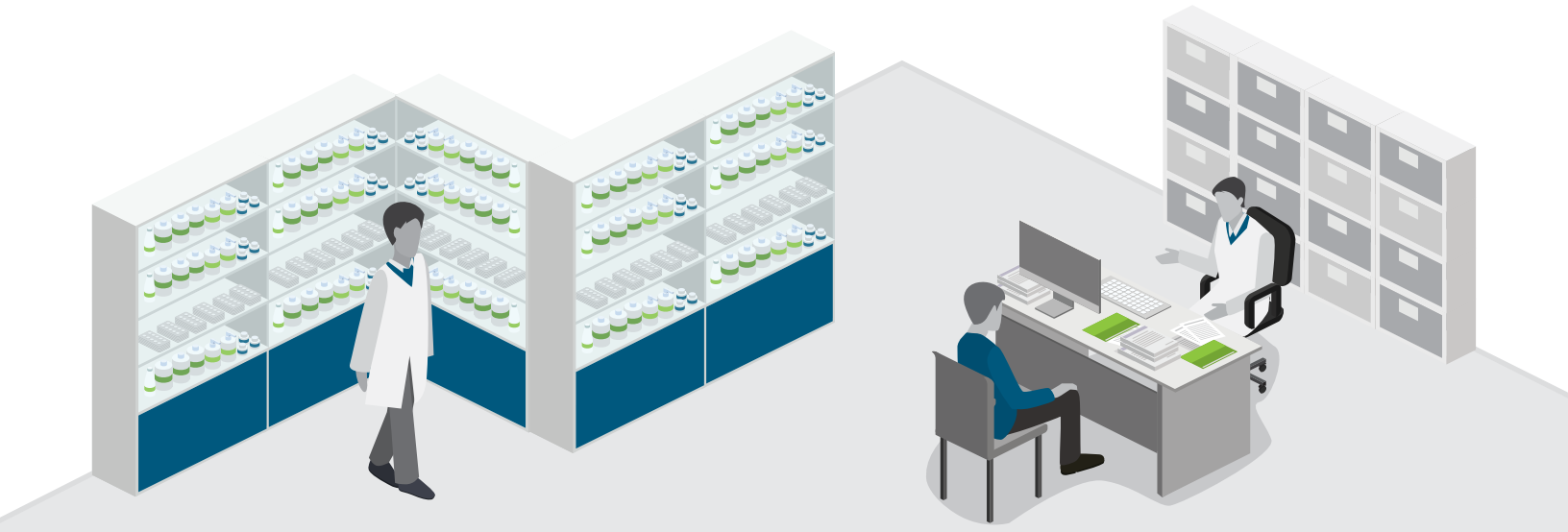
Leila: We've said that unless the payors put policies in place that effectively force that change in behaviour, it will never happen. I've had discussions with an oncologist who said when GSC introduced the biosimilars strategy and put it in place, he struggled because he was writing prescriptions for Neupogen®, and he was getting call-backs from the pharmacy. So he basically took it upon himself to learn about the biosimilar, Grastofil®, and became comfortable with the product, and has now shifted his practice to only prescribe Grastofil. So, as the result of our specific policy, he changed.

Ned: That's one thing we should mention: the success story of Grastofil… that's the one biosimilar that's absolutely dominating the market. For instance, it's at over 70 per cent and 90 per cent market share in Ontario under private and public plans, respectively. That's huge.

Marilyn: We should also talk about opioids since we're going to be further strengthening our policies next year. We're looking at some potential policy changes, such as limiting the initial days' supply for a new start on an opioid, then limiting a supply to 30 days at a time. Also we want to look at who our policy targets. Right now we target individuals on high doses of opioids, but there are people with concurrent use of other drugs that increases the risk of overdose. So those people will also be addressed. These are all things being done in the States that no one else is doing here.

Leila: Opioids are a multi-stakeholder problem. Everybody needs to do their part in tackling it. It's not a government thing, it's not a health care professional thing. And insurers shouldn't hide behind the argument that plan sponsors have "options" to tackle the problem. It's insurers and PBMs that have a responsibility on behalf of the plan sponsors to put strategies in place to help curb the opioid crisis.

FtS: This has been a great conversation with lots to think about. Thank you so much for talking to us.



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]
PROSTATE CANCER				
Traditional; High-cost; Specialty (Tier 5)	Erleada™ (apalutamide)	Prostate cancer occurs when prostate cells have uncontrolled growth and/or abnormal structure. It is the most common cancer to affect Canadian men with an estimated one in seven being diagnosed in their lifetime.[5] Since androgens (male sex hormones) play a key role in stimulating prostate cancer growth, androgen deprivation therapy (ADT) is used to lower the levels of these hormones (by lowering levels of testosterone to castrate levels) and slow the growth of cancer. This can be generally accomplished through surgical removal of both testicles (bilateral orchiectomy) or through the use of drugs (gonadotropin-releasing hormones [GnRH]). Those whose disease progresses despite being managed with ADT are considered to have castration-resistant disease, also known as castration-resistant prostate cancer (CRPC).[6] For those with early disease or non-metastatic (nm) CRPC (meaning the cancer has not spread to other parts of the body), there has historically been no standard of care, and patients were generally treated with ADT or secondary hormonal therapy to delay metastatic disease.[5] While nm-CRPC is associated with relatively mild symptoms, about one-third will progress and develop bone metastasis within two years (referred to as metastatic CRPC) which is associated with more symptomatic disease, decreased quality of life and overall survival.[7] Erleada is considered an androgen receptor (AR) inhibitor and has been shown to help delay metastases in patients' nm-CRPC. Erleada therefore fulfills an unmet need and is the first therapy to be approved by Health Canada for patients with nm-CRPC who are at high risk for developing metastases. It is administered orally (four tablets) once daily. Patients on Erleada should continue on ADT with a GnRH analog concurrently **or** have had a bilateral orchiectomy.	**$$$$** Approximately $41,384 per year	→ Specialty drug PPN → Requires prior approval

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] Prostate Cancer, Prostate Cancer Canada, http://www.prostatecancer.ca/.

[6] Overview of the treatment of castration-resistant prostate cancer, UpToDate, https://www.uptodate.com/.

[7] Korean J Urol. 2014 Mar; 55(3): 153–160.