

» Pharmacy – 2016 in review

Welcome to our round-table discussion featuring members of our GSC pharmacy team – **Sal Cimino**, **Ned Pojskic**, and **Leila Mandlsohn** – as well as **David Willows**, our vice president of Strategic Market Solutions.

David: In 2015 we wrote a lot about the new hepatitis C drugs which brought exploding costs in that class of drugs. What happened with the hepatitis C drugs in 2016?

Sal: I was recently looking at the data for one of our large plan sponsors and noted a significant drop in claims and costs. Much of this was anticipated because of the plan's demographics. The plan members who were part of the "hepatitis bulge" due to their age, got their treatment and are done. Leila, have you kept an eye on the rest of our book?

Leila: Yes! Overall the growth in spend for specialty drugs has decreased from the very challenging 2015. So the spend is *still going up*, but not as dramatically as it did last year. With fewer plan members starting the hepatitis C drugs, the decrease was largely driven by utilization of those drugs falling slightly. The cost per claimant for hepatitis C drugs is also going down.

Ned: Another point is that across payors, we're hearing that 70 per cent of the hepatitis C drug costs are now in the public realm, with 30 per cent remaining in the private space.

David: If the utilization and costs are now going down, what's the future for the hepatitis C drugs?

Leila: I understand that some provinces, which have traditionally paid for the more severe cases of hepatitis C, may open up the criteria for the less severe cases. The idea is to eradicate the disease, period.

In terms of the future for those drugs, in general we'll see a steady, slow decrease in claims because we're now going to be treating a different population of patients. So costs should continue to go down, but they will remain one of the higher priced classes. And any new hepatitis C drugs coming into the market are going to have to be competitively priced and offer an even shorter treatment duration.

David: Okay, if 2015 was the year of hepatitis C, what's the big story in 2016?

Sal: More of the same in terms of costs... I don't think this was unanticipated, but the general drug spend has gone up significantly over the last few years. The patent cliff has passed and there are fewer generics coming on the market that will offset the costs of all the new high-cost drugs.

Leila: Over the past five years the average cost per claim for biologic products has gone up by 25 per cent compared to the non-biologic drugs where the average cost per claim has gone down by two per cent... which makes sense. So to your point Sal, there are fewer generics – and fewer non-biologic drugs – coming to market.

Sal: We need to talk about the new biologics for cholesterol.

David: So our approach is to assess adherence to the first-line treatment before approving access to the more costly biologics?

Sal: Yes, what we've been doing is authorizing claims for the PCSK9 inhibitors [the biologics for cholesterol] when we have proof that the patient did **not** achieve their cholesterol target despite being adherent to their statin.

Leila: We do this because statins are highly effective drugs, and if the patient is adherent, they can often be successfully treated without adding a high-priced biologic.

Sal: Exactly.

David: Are physicians upset that we're not approving some of those claims after they have prescribed the biologic?

Sal: No. For Repatha specifically, we've seen several re-submissions from physicians, mostly because they're not giving us all the information we need to make an appropriate coverage assessment, so until we get the necessary information to review the claim, we will not issue an approval. On the other hand, submissions for Praluent, the newest PCSK9 inhibitor in the market, have been much more streamlined and are completed appropriately, so we've seen virtually no re-submissions.

David: This brings us to our specialty drug preferred pharmacy network [PPN] that we launched about 18 months ago. How has it grown and progressed? What's the feedback?

Sal: I think it has gone quite smoothly in the first year – any questions or concerns that have come up have been handled very well between us and HealthForward [our PPN partner]. New GSC clients are coming on and signing up quickly, so that's a feather in our cap.

David: So what percentages are we talking about for uptake?

Ned: When you're talking about our traditional group clients, we have over 90 per cent of our block of business in the PPN. There are very few who have deferred – it's by far the norm to be in the PPN.

Sal: And there are a few plan sponsors that already had their own PPNs, which they feel are sufficient. These are PPNs for all prescription drugs, not just specialty, so even without the extra services offered through HealthForward, there is already some cost protection built in.

David: We thought we were taking a chance with a "mandatory" PPN... that asking a plan member to change pharmacies would be an issue, but I haven't heard a lot of negative feedback about the customer experience.

Ned: Yes, it's smooth, it's working well. Half of plan members don't even have to change pharmacies, and those who did change, appear to be satisfied with the new pharmacy and their experience.

David: Any other 2016 topics we should talk about?

Ned: We're continuing to get our head around the impact of the emerging number of high-cost chronic drugs. Namely, that almost every chronic disease category is going to have a high-cost specialty drug associated with it. And those drugs are just starting to take off. That story will be an interesting one in the future. How will we keep people on the less expensive drugs that still work? Our approach on PCSK9 inhibitors becomes even more important: Is it applicable to other drugs for conditions like asthma or diabetes? Are we going to continue to invoke personal responsibility and not approve the claim when adherence to traditional, lower-cost but effective drugs is low? These questions are what we'll need to continue to investigate and talk to advisors and sponsors about as we head into the new year.

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
RHEUMATIC DISEASES				
High-cost; Specialty (Tier 5)	Brenzys™ (etanercept)	<p>Tumour necrosis factor (TNF) is a chemical substance produced by the body's immune system that leads to inflammation. Anti-TNF drugs are a class of drugs used to treat related inflammatory conditions such as rheumatoid arthritis (RA) and ankylosing spondylitis (AS).</p> <p>Brenzys is the second anti-TNF subsequent-entry biologic (SEB) to be available in Canada following the approval of Inflectra® in 2014.</p> <p>Based on demonstrated similarity to the reference product Enbrel®, Brenzys was approved by Health Canada for two of Enbrel's five indications: RA and AS.</p> <p>Brenzys is administered by injection once weekly and offers a more affordable option for patients with RA and AS, which accounts for 49% of Enbrel use.⁵</p>	<p>\$\$\$\$</p> <p>Approximately \$15,860 per year</p> <p>Represents a 25% discount compared to the originator biologic Enbrel</p>	<p>→ Specialty drug PPN</p> <p>→ Requires prior approval</p>
High-cost; Specialty (Tier 5)	Simponi™ (golimumab)	<p>Spondyloarthritis is an umbrella term for the family of inflammatory rheumatic diseases that cause arthritis. Spondyloarthritis involves the site where ligaments and tendons attach to bones. It can be classified as axial (primarily affecting the spine and pelvic joints) or peripheral (mostly affecting arms and legs). In a further subtype called non-radiographic axial spondyloarthritis (nr-axSpA), specific changes affecting the sacroiliac joints (joint connecting the triangular bone at the bottom of the spine with the pelvis) are absent.⁶</p> <p>Simponi is the only biologic agent currently approved in Canada for the treatment of nr-axSpA. Simponi now offers a new treatment option for this relatively new classification of patients with nr-axSpA who continue to have active disease despite standard treatment with NSAIDs (non-steroidal anti-inflammatory drugs). Simponi is administered by injection once per month.</p>	<p>\$\$\$\$</p> <p>Approximately \$18,662 per year</p>	<p>→ Specialty drug PPN</p> <p>→ Requires prior approval</p>

CANCER

High-cost; Specialty (Tier 5)	Imbruvica® (ibrutinib)	<p>Lymphoma occurs when the lymphocytes (a type of white blood cell) grows uncontrollably. It is the most common blood cancer and has two main forms: Hodgkin and non-Hodgkin lymphoma (NHL). Mantle cell lymphoma (MCL) is a rare, aggressive, and incurable subtype of NHL that is often diagnosed at an advanced stage. In MCL, although patients generally respond to initial treatment, they often relapse within a few years.⁷ There are approximately 500 newly diagnosed cases of MCL each year and it most commonly occurs in adult men over the age of 60.⁸</p> <p>Imbruvica is a first-in-class orally administered once-daily regimen. Currently, there is no standard of care for relapsed (disease returns after responding to initial treatment) or refractory (did not respond to initial treatment) MCL. Available treatments are scarce due to limited effectiveness and severe side-effects. Imbruvica offers a new treatment option that fulfills an unmet need for patients with relapsed and refractory MCL.</p>	<p>\$\$\$\$\$</p> <p>Approximately \$132,349 per year</p>	<p>→ Specialty drug PPN</p> <p>→ Requires prior approval</p>
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HEPATITIS C

High-cost; Specialty (Tier 5)	Epclusa™ (sofosbuvir/ velpatasvir)	<p>New hepatitis C treatments continue to emerge and Epclusa is a new treatment option that treats all genotypes of hepatitis C, offers high cure rates (91%-100%), good tolerability, and a simplified treatment regimen regardless of genotype, stage of liver disease, or prior treatment experience.</p> <p>In contrast to currently available treatments, Epclusa may offer shorter treatment durations, ribavirin-free courses, and fulfills an unmet need for certain genotypes (i.e., G5/6) where there is a lack of treatment options.</p> <p>Epclusa is administered as a single-tablet once-daily regimen for 12 weeks. Patients who have complications related to late-stage liver scarring (decompensated cirrhosis) should take ribavirin (RBV) in addition to Epclusa.</p>	<p>\$\$\$\$\$</p> <p>Approximately \$60,000 per year</p>	<p>→ Specialty drug PPN</p> <p>→ Requires prior approval</p>
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¹High-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 high cost if clinical evidence warrants)

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 Based on GSC's book of business in 2015.

⁶ Spondyloarthritis, American College of Rheumatology, <http://www.rheumatology.org/1-Am-A/Patient-Caregiver/Diseases-Conditions/Spondyloarthritis>

⁷ Mantle Cell Lymphoma: Relapsed/Refractory, http://www.lymphoma.org/atf/cf/%7BAAAF3B4E5-2C43-404C-AFE5-FD903C87B254%7D/LRF_FACTSHEET_MCL_RR_2013.PDF?auid=12730367

⁸ Health Canada Approves Ibrutinib for Mantle Cell Lymphoma, <http://www.lymphoma.ca/research/health-canada-approves-ibrutinib-mantle-cell-lymphoma>

BEHIND THE COUNTER



LET'S TALK ABOUT OPIOIDS

The November 2016 issue of *The Inside Story* described the opioid crisis in Canada today and its background. To gain some on-the-ground insight, we talked to GSC pharmacist Chris Leung about how opioids are being prescribed and used.

Follow the Script: Chris, thanks for joining us. We're seeing stories about opioids in the news every day. In your experience, who is being prescribed opioids?

Chris: The main population coming to me with prescriptions for opioids is people experiencing pain from things like workplace-related injuries or car accidents. Usually people with less severe pain – like dental pain – are taking less potent opioids like Tylenol 2 or 3.

FtS: This very high-profile and worrisome situation with opioids didn't happen overnight. How did we get here?

Chris: It all started because opioids were never meant to be used for such a wide range of pain control. Strong drugs like opioids were originally used for soldiers who suffered serious injuries on the battlefield. But later on, in modern-day medicine, plant-based and synthetic opioids started to be developed. The pharmaceutical manufacturers wanted a return on their investment in research and development, so they marketed these drugs for broader pain control – for cancer, palliative care, and workplace injuries; conditions where existing drugs were not believed to be strong enough to make a difference for some patients.

FtS: So this is why the use of opioids has increased so much?

Chris: When you first start treating someone for pain, you start by giving them lower doses and it generally works well. But as the body gets used to the drug, the effects wear off faster; therefore, to get same level of pain control, the dosage keeps getting increased.

Once opioids started being commonly used, there was a shift in mentality. As more opioids and stronger opioids were developed, patients began demanding them – their goals weren't necessarily to just control the pain; in more and more patients it was to **feel no pain**. Patients did not want to feel any pain at all. So in the early 2000s, you kept seeing increases in opioid dosages to meet this desire.

FtS: Weren't there limits for how much a doctor could prescribe to someone?

Chris: Back then there were no official guidelines for a maximum dosage, so the dosage kept going up. These patients had no pain but they were "doped up" and couldn't function normally – they were challenged to complete tasks that require concentration.

Today there are guidelines in place so that opioids are prescribed more sparingly. There's a maximum dose patients should be prescribed plus they are advised they can manage pain through other ways – like acupuncture, physiotherapy, occupational therapy, massage therapy, and psychotherapy. It comes down to how we treat the whole person. People can learn to cope with the pain.

FtS: Okay, so these products have been misprescribed or overprescribed because patients can't have the total recovery they desire – they want to be 100 per cent pain free but often this isn't realistic. Would you say that we're at a point where our society is using these drugs in ways in which they never should have been used?

Chris: Yes, that's fair to say.

FtS: Shouldn't we expect doctors to know how the drugs should be used?

Chris: Not all doctors are trained in pain control. Historically, it's not an in-depth subject in medical school. Doctors who specialize in pain control have more extensive training – they have a greater understanding of the patient's condition and the potential treatments. If patients need counselling and support to manage their discomfort, they can be referred to physiotherapy, occupational therapy, or counselling, etc. And, of course, their pharmacist can help too. All these health practitioners are involved in what I call a "circle of care." When everyone does their part in the patient's circle of care, then that person will be better able to cope with their situation. And they'll understand they can come to manage their pain, but not necessarily eliminate it.

FtS: If doctors aren't trained but are prescribing these drugs, what's the pharmacist's role in being a gatekeeper?

Chris: You have to assess the individual patient: maybe the drugs are appropriate for their situation, maybe not. It's important that trust in the pharmacist-patient relationship develops in these instances. If there's trust, then the pharmacist can start assessing and making recommendations to help with pain control which may include changes to medication. Even when a patient doesn't seem open to the message, they may go away and think about it and eventually be willing to talk further with the pharmacist. And we hope that sooner rather later they'll talk to their doctor about the issues we raise.

FtS: Is it easy to tell when a person has a problem with opioids?

Chris: I'm not expert enough to tell whether a person might have an opioid problem, but other pharmacists may be able to – if they have more extensive training – like pharmacists who work in addiction clinics.

The body can be a funny thing and everybody is different. You can't tell who is going to develop an addiction problem. Some people can take these drugs then wean themselves from them pretty easily. But others are more susceptible to becoming dependent or addicted to the opioid. A pain specialist is really the most qualified person to figure out a patient's problems with opioids and help them.

FtS: What's the difference between being dependent and being addicted?

Chris: The terms seem to be used interchangeably, but if a person is dependent it's that they have a physical need for the drug. He or she can suffer withdrawal symptoms when the drug is stopped. A person who is addicted has dependence but also has a change in behaviour caused by changes in the brain after continued use of opioids. Using the drug becomes the main priority of that person regardless of the harm this may cause themselves or others. Addiction is what leads to compulsive behaviour and devastates lives.

FtS: Is all this really a new thing?

Chris: No, addiction is nothing new. But one thing about opioids is when society moves to restrict an opioid, then a population's drug of choice changes. For example, when OxyContin was changed to OxyNEO, people moved on to fentanyl.

FtS: We've seen a lot about fentanyl – is it really more addictive than some other opioids?

Chris: Yes, it's a synthetic narcotic and much more powerful and addictive than other prescription opioids. And then there are very strong street drugs out there like the animal tranquilizer, carfentanil. Dealers can get access to this product through the mail from China – and they don't care who they're selling it to.

FtS: In the end, with all these concerning stories of misuse and harm, is there even a place for opioids in medicine?

Chris: Yes, but like everything else, they need to be used in moderation. People taking opioids for chronic pain should get a maximum one-month supply, not a three-month supply, that way there's regular follow-up care, and the doctor has the opportunity to assess the patient's pain control monthly. By dispensing these drugs in smaller quantities, there will be less excess supply that might end up on the street.