EXPANDED ACCESS AND COST SAVINGS WITH BIOSIMILARS: A DRUG ACCESS NAVIGATOR'S POINT OF VIEW

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BACKGROUND

It has been over 10 years since the first biosimilar was approved in Canada, which was somatropin[1] and since then, many others have followed. The first one used in the Toronto cancer clinic where I work was Grastofil® (filgrastim). This drug, from Apobiologix, was approved by Health Canada in 2016[2] and we started using it when it was added to the public (ODB) drug formulary as a general benefit as the innovator product, Neupogen® (filgrastim) had restrictive reimbursement criteria associated with its use and was reserved for use in special situations.[3] The difference in status of reimbursement between Grastofil® and Neupogen® encouraged our centre to switch all public reimbursement patients to Grastofil®. Over the next few pages, this article will attempt to share my viewpoint of how biosimilars play an important role in expanding access and driving cost savings within the healthcare system, as a drug access navigator (DAN).

WHAT IS A DAN AND HOW CAN THEY HELP[4]?

Drug Access Navigators or DANs help take on some of the burden of getting medication for patients so that they can focus on their treatment instead. Our primary goal is to remove the financial burden from the patient and because of the increasingly complex system to obtain drug coverage, there is an Oncology Drug Access Navigator in nearly every cancer clinic in Ontario. Navigators act as resident experts on drug coverage and criteria for coverage. We facilitate drug coverage by:

- Accessing government funding through programs such as the Exceptional Access Program (EAP) and Special Access Program (SAP)
- Accessing patient support programs (PSP)
- Finding other reimbursement means for unfunded drug costs
- Helping with applications to the Trillium Drug Program

For patients paying with a private insurance plan, the DAN can help with:

- Three-way calls between the patient, insurance company and DAN
- Submitting prior authorization forms
- Requesting exceptions to the plan formulary
- Submitting renewals when required
- Appealing negative decisions

And finally, DANs also help connect patients to other different mechanisms that may provide access to therapies. These patient programs can offer critical help and often include:

- Copay assistance
- Compassionate free drugs

- Providing free bridging drug supply while waiting for public/private drug coverage
- Nursing phone support

INDUSTRY SUPPORT

When biosimilars first received approval in Canada, the DAN community received much-needed support from the manufacturers of these products which is a critical step in ensuring adoption and widening access as our comfort level with these products must be high in order to advocate for their use and counsel patients.

Some of the steps taken by the manufacturers included:

1. providing regular educational in-services to clinic staff

2. ensuring clinical staff understood this new class of drug from a safety and efficacy perspective

3. explaining the differences between biosimilars and generics from a manufacturing perspective

When bevacizumab and trastuzumab biosimilars were approved, most new patients were switched according to specific criteria from the provincial government.[4] Intravenous therapies like these tend to use Drug Access Navigator resources less than oral and injectable medications. However, industry-developed patient support programs launched with these therapies ensured that those needing these therapies for non-publicly funded treatment indications, could still get access to therapy in a timely manner without compromising the patient's health.

PHYSICIAN AND PHARMACY SUPPORT

In considering the adoption of biosimilars such as Grastofil® and Lapelga®, our entire cross- functional team comprised of physicians, nurses, pharmacists and DANs would review the clinical and safety data[5] and discuss the practical implications for transitioning all of our patients from the reference product to the biosimilar product. Physicians, of course, want to ensure continuity of care, sustained efficacy for patient management of disease and minimal side effects when making the decision to switch products. From an in-hospital pharmacy perspective, the emphasis is on product safety for our patients, which encompasses the use of one single product whenever possible in order to reduce the potential for mix-ups by healthcare professionals as well as patients.

PATIENT SUPPORT PROGRAMS

As mentioned earlier, one of the critical components of a DAN's day-to-day job is to ensure there is no patient who is unable to receive their therapy due to reimbursement or coverage gaps. When Grastofil® and Lapelga® became available in Canada, Apobiologix launched a patient support program (PSP) entitled ANSWERS.[6] As a DAN, I utilize the ANSWERS program every day so that my patients can get access to treatment as soon as possible without any out-of-pocket cost. The ANSWERS program has provided very similar services and offerings as the reference product's patient support program which has made the transition for me quite easy.

Another important tool in the DAN toolbox to increase access and to make the patient experience easier has been the launch of another new patient support program through Biosimilars Canada, the national association representing Canada's biosimilar medicines industry. This all-in-one patient support program will provide a common suite of PSP services for Biosimilars Canada industry members going forward that can be customized to meet the individual needs of the therapy, the biosimilar sponsor and payers and is fundamentally an important tool meant to allow the transition from one biosimilar to another for clinics and patients in case of back orders. The Biosimilars Canada Patient Support Program platform will create a seamless and simple process for patients and physicians, without any compromise to the quality of services provided to patients.[7] For example, if a patient is on one biosimilar through their private insurance plan and that drug goes on back order, the patient will still need therapy and will still need copay assistance. This new PSP will allow the patient to gain access to their needed therapy without supply interruption and ensure continuity of care.

EXPANDED ACCESS WITH BIOSIMILARS:

When it comes to supportive medications, the Drug Access Navigator's role is key. These therapies are typically obtained from retail pharmacies and paid for out-of-pocket by some patients. DANs are the bridge between the hospital / clinic, the patient, and the payer-- whether that be private or public insurance. The

impact of our role is reflected in the fact that when newly diagnosed cancer patients are told they will not have to pay anything for their medications as a result of the support from the Patient Support Program, the patients are incredibly thankful and relieved to have this financial burden removed. I often hear and see first-hand that patients are fearful of not being able to afford these medications as many cannot work during treatment.

For some biosimilar drugs like bevacizumab, trastuzumab and rituximab, the role of the DANs is less involved as these intravenous therapies are fully covered through Cancer Care Ontario. However, the DAN can still play an important role in helping to fill coverage gaps. This may mean co-pay assistance is needed for a privately-insured patient or a request to a manufacturer for compassionate use and bridging of product is required. Many of these therapies can cost thousands of dollars per dose, and a 20% co-pay from a private drug plan can be both cost prohibitive and stressful for a cancer patient to deal with.

EASE OF ACCESS TO DRUGS

The situation in terms of accessing these biosimilar therapies will naturally differ from hospital to hospital and patient to patient. As an example, for granulocyte-colony stimulating factor (G-CSF) therapies, my hospital owns its outpatient pharmacy. This means nearly all patients get their drugs from our in-hospital pharmacy and this has eliminated issues that come up when using other outpatient pharmacies, such as the consistency of supply and pharmacist familiarity with underlying comorbidities and lifestyle issues to maximize adoption and persistence with medication regimens.

For Lapelga®, private insurers have almost always covered it without a prior approval process required and this, unlike the process with the reference product, has been a welcome added measure of time saving for myself and my patients.

With the support of the various patient support programs, we have been able to access biosimilar therapies for patients while waiting for their public or private coverage to kick in.

COST SAVINGS WITH BIOSIMILARS

For G-CSF drugs like Grastofil® and Lapelga®, the typical cost savings that accrue to the system on drug pricing alone is around 20-30% less than the reference product.[8] Although, this has meant less revenue to the hospital pharmacy it has meant a tremendous cost savings to our healthcare system across the board which must not be overlooked as being the fundamental rationale for making biosimilars available in this country.

As more biosimilar therapies become available, the anticipated cost savings should total hundreds of millions of dollars per year across Canada.[8] This is critical because, at the same time, new innovative drugs are being approved with even larger prices and the system needs a mechanism to deliver savings today in order to make financial room for newer therapies for which there is no current biosimilar option. As patients are living longer with today's treatment options available to them it is imperative that biosimilars play an important role in achieving the cost savings that our health system so desperately needs.

DRUG ACCESS CANADA

As a final thought, I would also like to introduce you to a new association focused on accessibility of medications called Drug Access Canada (DAC). The goal of DAC is to ensure patient support program services and offerings are made available to all healthcare professionals across Canada, including oncology / hematology programs, but also for other therapeutic areas like rheumatoid arthritis, multiple sclerosis, and rare diseases. Our new website at www.drugaccess.ca is a great way for physicians, nurses, social workers, and other allied healthcare professionals to see what the various patient support programs are offering to clinics and patients.

CONCLUSION

I believe our centre's experience with biosimilar implementation is similar to other cancer clinics in Ontario since we are all bound by the same provincial formulary and private insurance restrictions for our patients. The key to ensuring continued access and reductions in costs involve constant communication among clinics and the sharing of experiences so that all patients receive equitable access and care.

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Alan Birch is an Oncology Drug Access Navigator in Toronto, Canada. He is a pharmacy technician by background and has been in his current role for the past 8 years. He is a member of the Oncology Drug Access Navigators of Ontario (ODANO) and has recently launched a new national association for healthcare professionals called Drug Access Canada.