



**A PRIMER ON
THE VALUE OF
SPECIALTY
PHARMACY
SERVICES FOR
PATIENTS AND
HEALTHCARE
SYSTEMS IN
CANADA**

Report by:
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Association of Canada

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EXECUTIVE SUMMARY

- This report examines the integral role of pharmacy, pharmacists, and the pharmaceutical supply chain in managing the safety, effectiveness, and administration of these complex specialty medications to best support patients in their communities.
- A collaborative approach between the government and the pharmacy sector is needed to ensure pharmacy's role in specialty medication evolves effectively to promote the continued delivery of innovative patient care.
- Through pharmacy's accessibility, high level of expertise, and ongoing support, patients taking specialty medications can enjoy increasingly positive health outcomes, and healthcare systems and payors can maximize the value of these high-cost, life-saving treatments.

This report describes the services pharmacy provides to patients taking specialty medications, and the associated value pharmacy delivers in the healthcare system.

Innovations in the field of specialty medications are changing the story of disease by improving outcomes for patients, and for the healthcare system. These innovations offer hope and, in some cases, a cure, where other therapies were limited in their effectiveness.¹

Pharmacy has always engaged patients in the treatment of their disease by promoting understanding, participation, and adherence to their drug therapy. However, for specialty medications, pharmacies are increasingly managing many other aspects of this unique drug therapy, including shipping and handling, reimbursement navigation, monitoring, and administration.

All participants in the healthcare system share responsibility for optimizing the value of the high cost of specialty medications. With these more complex therapies comes more complex care. As we move toward increasingly individualized medicine, patient care will become equally complex.

For patients and the healthcare system to realize the full benefit of specialty medications, the services supporting the patient journey must themselves be supported and understood. A collaborative approach between the government and the pharmacy sector is needed to ensure pharmacy's role in specialty medication evolves effectively to promote the continued delivery of innovative patient care.

This report examines the integral role of pharmacy, pharmacists, and the pharmaceutical supply chain in managing the safety, effectiveness, and administration of these complex specialty medications to best support patients in their communities.

The report also details how pharmacies personally interact with patients in the overall management of their specialty drug therapy, and how patients rely upon their pharmacist to provide this guidance and support.

Pharmacy's participation in the administration of specialty medications has contributed to improved patient outcomes, notably in education, ensuring access to therapy, improving adherence, and providing adverse event monitoring and reporting.

Finally, the report recommends how pharmacy can continue playing a critical role in caring for patients taking specialty medications. Through pharmacy's accessibility, high level of expertise, and ongoing support, patients taking specialty medications can enjoy increasingly positive health outcomes, and healthcare systems and payors can maximize the value of these high-cost, life-saving treatments.

¹https://www.medicinenet.com/biologics_biologic_drug_class/article.htm#what_are_the_medical_uses_for_biologics?



INTRODUCTION

- Not long ago, patients with complex and debilitating diseases had very few treatment options. For patients responding well to specialty medications, this drug therapy is rewriting their life story.
- These more complex medication therapies typically require frequent dose and regimen adjustments from the patient's healthcare provider – most often, the community pharmacist.
- This approach also means much closer communication between the pharmacist, labs and prescribers to monitor therapy safety and effectiveness. Monitoring patients for adverse events extends to pre-administration, during administration and post-administration.

In the face of life-altering disease, patients and their loved ones look for hope, devoting countless hours and energy searching for innovation – a cure, treatment, or anything to offer relief. In recent years, a growing number of patients are finding this innovation in the area of specialty medications.

Specialty medications have revolutionized the treatment of complex illnesses. Their capabilities, many of which are still under research, are incredibly impressive.

Many specialty medications have cured diseases, such as Hepatitis C, and reverse the course of others, including HIV and IBD, offering hope where other therapies fall short.

The list of diseases that respond to specialty medications includes everything from rheumatoid arthritis, psoriasis, and macular degeneration, to multiple sclerosis and cancer.

SPECIALTY MEDICATIONS TREAT COMMON ILLNESS

Patients are increasingly turning towards specialty medications as a way to treat and cure some of the most well-known debilitating illnesses including:

- CANCER
- RHEUMATOID ARTHRITIS (RD)
- INFLAMMATORY BOWEL DISEASE (IBD)
- MACULAR DEGENERATION
- HEPATITIS C
- HIV
- PSORIASIS
- MULTIPLE SCLEROSIS (MS)

Not long ago, patients with complex and debilitating diseases had very few treatment options. For patients responding well to specialty medications, this drug therapy is rewriting their life story.

Specialty medications that have cured diseases like Hepatitis C have avoided lifelong therapies and surgeries for patients. Specialty medication treatments for HIV have prolonged life for those suffering from this virus. These patients are now effectively living with a managed chronic disease and can be productive members of society. Those with debilitating diseases like IBD and RA can work and be productive because these medications have helped manage their symptoms. These patients would have otherwise been unable to function or perform their Activities of Daily Living (ADLs), which would have been costly to the healthcare system and employers – due to frequent absenteeism, short- and long-term disability claims.

These more complex medication therapies typically require frequent dose and regimen adjustments from the patient's healthcare provider – most often, the community pharmacist. This approach also means much closer communication between the pharmacist, labs and prescribers to monitor therapy safety and effectiveness. Monitoring patients for adverse events extends to pre-administration, during administration and post-administration.



DEFINITION OF SPECIALTY PHARMACY

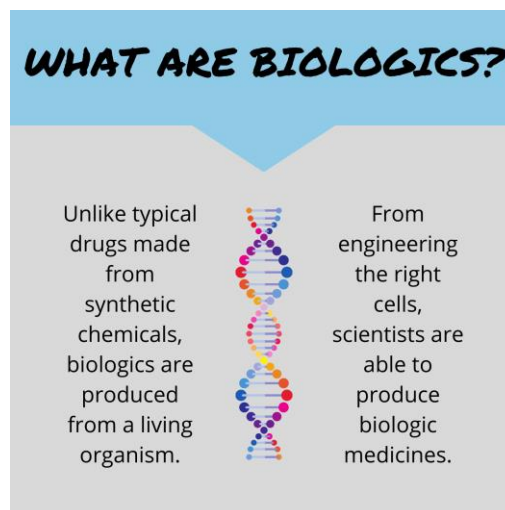
- Specialty medications differ from traditional medications because they require specialized services to manage complex diseases and drugs.
- To be clear, not all specialty medications are biologics, though many specialty medications belong to this drug classification.
- Administration of specialty medications may require specialized training or devices, as well as additional medical services and oversight.

Specialty medications differ from traditional medications because they require specialized services to manage complex diseases and drugs.

Many specialty medications are biologics and are administered by injection or infusion. They often require refrigeration in order to maintain their integrity and effectiveness. Administration of biologics may require specialized training or devices, as well as additional medical services and oversight. **To be clear, not all specialty medications are biologics, though many specialty medications belong to this drug classification.**

Traditional medications are synthesized through chemical reactions that generate a final product with a specific chemical structure.

However, biologics are developed using DNA technology whereby *living cells* are engineered to “manufacture” a specific protein or drug. Biologics are typically more difficult to produce and usually more expensive than traditional medications.



DEFINITION OF SPECIALTY MEDICATIONS

Specialty Medications:

- Treat chronic, debilitating diseases
- Treat common **and** rare conditions
- Cost + \$10,000/year
- Benefit from enhanced patient education from healthcare providers to maximize safety and effectiveness
- Need to meet specific delivery and handling requirements
- Involve rigorous clinical monitoring
- Requirement for individualized dosing and patient education beyond traditional dispensing to maximize drug effectiveness, safety, and appropriate use
- Typically have detailed testing regimens to promote greater likelihood of successful outcomes for patients



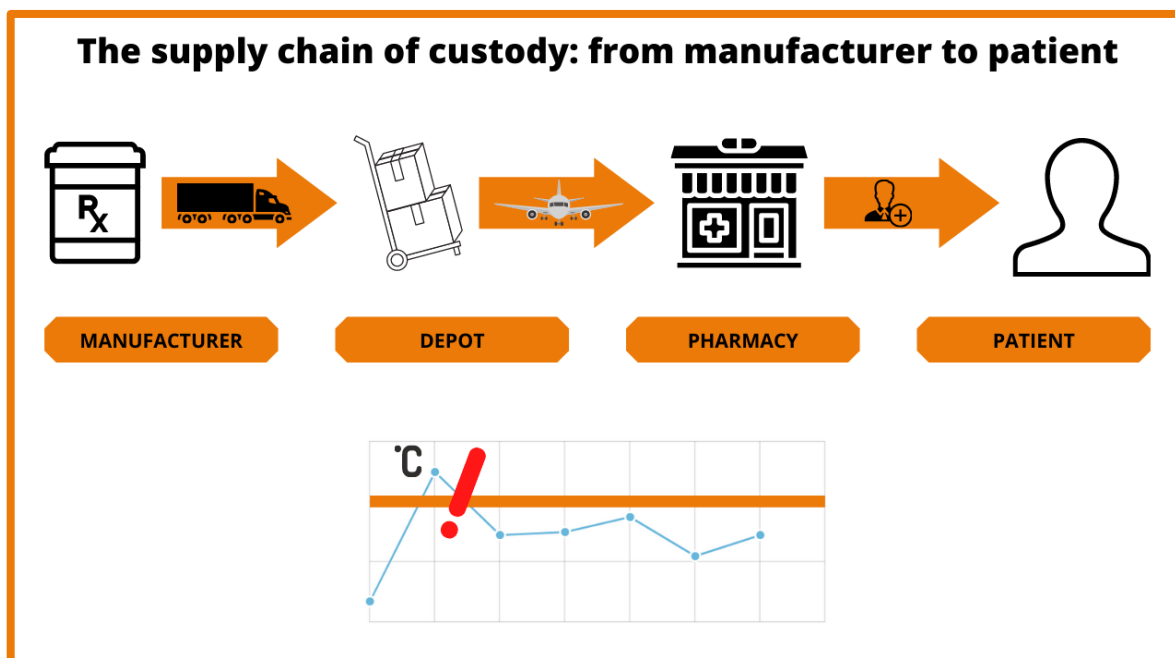
PHARMACY'S ROLE IN PROMOTING PATIENT SAFETY

- Pharmacies are instrumental in maintaining the cold chain and in preserving the safety and effectiveness of specialty medications. They protect the integrity of the product, which can spoil easily if not carefully handled.
- Where specialty medications are concerned, pharmacists' role in monitoring and educating patients is vital to achieving successful treatment outcomes. Supporting patient-centered care involves pharmacists assessing patient readiness for therapy, monitoring effectiveness, and advising patients through the management of side effects.
- For the healthcare system, and for the payors who fund specialty medications, this sustained emphasis on achieving the conditions for safety and effectiveness is critical. Maintaining the safety of specialty medications helps payors achieve the best value for their cost and, most importantly, promotes patient safety and improved health outcomes.

Given the complexity of specialty medications, their handling, monitoring, and administration need to be carefully coordinated throughout the pharmacy supply chain, to maintain product integrity and promote patient safety.

Maintaining Safety throughout the Pharmacy Supply Chain

Where refrigeration is required, pharmacy ensures the product remains in a “cold chain”, a controlled supply chain that maintains the necessary temperature to keep the product safe and effective. To be correctly maintained, the cold chain is managed and monitored throughout the pharmacy distribution channel, from the point of manufacturing to the point of patient administration – including throughout the shipping process. Pharmacies even coordinate dispensing with clinic administration to ensure this cold chain is preserved.



Even the slightest temperature fluctuations can compromise medication safety and effectiveness in this class of drug therapy. Pharmacies are instrumental in maintaining the cold chain and in preserving the safety and effectiveness of specialty medications. They also protect the integrity of the product, which can spoil easily if not carefully handled.

| Patient Need | Consequence if Need Unmet | Pharmacy Service to Address Need | Time Required (mins) |
|---|---|---|----------------------|
| Product needs to arrive at specific place for administration | No drug where and when needed for patient <ul style="list-style-type: none"> Inconvenience; therapy abandonment Missed or delayed dose Dosing issues Risk of drug waste | Coordination of delivery with patient appointment at clinic | 10-15 |



| | | | |
|---|---|---|------|
| Product needs refrigeration – cold chain | Product integrity may be compromised Possible negative impact on therapy outcome Significant risk of drug waste | Packaging, handling and temperature controlled and monitored shipping | 5-15 |
|---|---|---|------|

Noting the sensitivity associated with proper storage and handling of specialty medications, in some cases, the pharmacy dispenses this medication to the patient or caregiver only in the quantity of a *single immediate dose*.

While most pharmacies deliver prescriptions, the unique aspect of the cold chain makes these medications much more costly to maintain overall. These medications also require specific packaging and frequent temperature monitoring to protect product integrity further. The cost of cold chain packaging ranges from \$25.00 to \$50.00 per shipment depending on the product and an additional 5 – 15 minutes to prepare the product for shipping.² Because they are often administered by infusion, they frequently are delivered directly to the infusion clinic and are coordinated to arrive in time for the patient's appointment. Respecting the expense of these products to patients and payors means pharmacy's role is critical to protecting against spoilage and wastage.

Pharmacists Educate and Monitor their Patients

Where specialty medications are concerned, monitoring and education are vital to achieving successful treatment outcomes. Supporting seamless, patient-centered care also involves pharmacists assessing patient readiness for therapy, monitoring effectiveness, and advising patients through the management of side effects.

| Patient Need | Consequence if Need Unmet | Pharmacy Service to Address Need | Time Required (mins) |
|---------------------------|--|---|----------------------|
| Adherence | Therapeutic outcome will be sub-optimal Disease progression | Patient Education/engagement Adherence support | 5-30 |
| Injection Training | Additional cost for healthcare provider to inject Treatment delays or abandonment Disease progression | Patient Education | 30-50 |
| Other assistance | Compromised disease and/or therapy understanding Disengagement Disease progression | Patient Education | 15-60 |
| Onboarding | Failure to assess Pre-treatment vaccine status, drug interactions Drug-disease interactions Allergies Co-morbidities Lab work schedules Risk of inappropriate drug use | Medication Management, confirm appropriateness of therapy | 10-30 |

² Neighbourhood Pharmacy Association of Canada, survey of members, August 2018



| | | | |
|----------------------------------|--|--|-------|
| Side Effects | Patient may stop drug early or unnecessarily Disease progression Risk of toxicity | Education and side effects management | 5-60 |
| Pre and Post Care support | Mandatory lab work missed leading to delayed treatment (and potential drug waste) Hospitalizations Additional health issues Failure to change therapy where indicated | Medication Management, ongoing patient contact | 10-20 |

In our survey, the time spent on these vital patient care services was estimated and is shown in the table above. The amount of time spent with each patient depends on the drug therapy and the needs of the patient. Every patient goes through an onboarding process and every patient will receive adherence counseling but the other services will vary from patient to patient.

Pharmacy's vital role in patient monitoring and education ensures compliance with the drug therapy protocol. Pharmacists also confirm that the therapy remains appropriate for the patient in the context of other conditions they may have, or concurrent treatments they may be undergoing.

Understanding the specific requirements of specialty medications – from storage and handling to patient monitoring and minimizing side effects – requires coordination between manufacturer, distributor, pharmacy, provider, patient, and caregiver.

For the healthcare system, and for the payors who fund specialty medications, this sustained emphasis on achieving the conditions for safety and effectiveness is critical. Maintaining the safety of specialty medications helps payors achieve the best value for their cost and, most importantly, promotes patient safety and improved health outcomes.





OUTCOMES FOR PATIENTS, WORKPLACES AND CAREGIVERS

- Pharmacists frequently interact with caregivers in the administration, monitoring, and continued education needed for specialty medications, providing accessible care with greater ease of follow up.
- With healthier employees, employers benefit from increased productivity and reduced short- and long-term disability.
- A healthier patient makes more meaningful contributions to the workplace, is less reliant on caregivers and the healthcare system, and has a greater sense of independence.

While the financial cost of specialty medications is high, the benefit they provide to patients is immeasurable. It's impossible to place a value on the health and quality-of-life improvements these drugs deliver. The benefits extend well beyond the patient. A healthier patient makes more meaningful contributions to the workplace, is less reliant on caregivers and the healthcare system, and has a greater sense of independence.

Healthier Workplaces

With healthier employees, their employers benefit from increased productivity and reduced short- and long-term disability. In the case of the IBD patient (see inset below), the transition from disease to remission enabled his triumphant return to work and productivity.

Patient Story


Living with Inflammatory Bowel Disease

A doctor shares how his patient's life improved following the introduction of a specialty medication to his drug-therapy regimen:

— “ —

“I recall one patient in particular. He was starting his specialty medication – in this case, a biologic, for his IBD. He was gaunt, off work, and was unable to do much of anything. He seemed afraid and too young to be so frail. After only a few months of taking his new specialty medication, I saw him again. At first, I didn't even recognize him. He looked like a different person! He was smiling and had gained weight. He was happy. The biggest changes for him? He had returned to work and was strong enough to carry his toddler again.”

— ” —



Compelling statistics concerning IBD's impact illustrates the importance of striving for optimal treatment of this and other chronic diseases. In Canada, IBD contributes to an estimated \$629 million in lost productivity and \$1.57 billion in medical absenteeism (absence for medical appointments or hospitalization). Overall indirect health-related costs of IBD in Canada are estimated at \$1.29 billion.³

Impact on Caregivers

Caregiving in Canada has also been studied and quantified in relation to patients with long-term health conditions or disabilities.

³ Impact Report 2018, Crohn's and Colitis Canada



We know caregivers are more likely to experience adverse health, career, financial and psychological consequences when tending to a friend or family member experiencing illness or disease.⁴ Pharmacists frequently interact with caregivers in the administration, monitoring, and continued education needed for specialty medications, providing accessible care with greater ease of follow up.



Statistics Canada reports that more than 8 million Canadians provide informal care to a family member or friend.⁵ Almost 35% of Canada's workforce provides informal, unpaid work while working, and 1.6 million caregivers took time off work to provide care.⁶

The estimated economic value of unpaid caregiving in Canada exceeds \$25 billion annually.⁷ Governments and healthcare systems often do not sufficiently acknowledge the valuable resource caregivers provide to patients requiring additional support and assistance in managing their health condition.



⁴ <https://www150.statcan.gc.ca/n1/pub/75-006-x/2013001/article/11858-eng.htm#a7> Family Caregiving: what are the consequences? Stats Canada 2013

⁵ Statistics Canada. 2012. "Portrait of Caregivers"

⁶ Report from the Employer Panel of Caregivers. 2015. "When Work and Caregiving Collide"

⁷ National Institute on Ageing. (2018). Why Canada Needs to Better Care for Its Working Caregivers. Toronto, ON: National Institute on Ageing White Paper.



RESPONSIBLY MANAGING HIGH- COST SPECIALTY MEDICATIONS

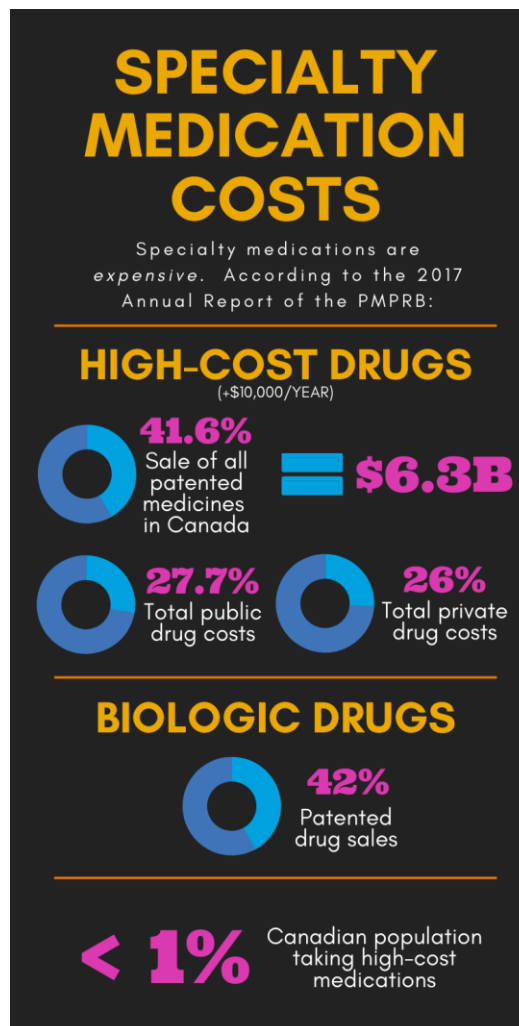
- Drug therapy problems are a key driver of medical resource utilization. As medication experts, pharmacists are well-positioned to manage drug therapy and reduce the cascading costs associated with non-optimized treatments.
- Pharmacists' role is vital for all patients with chronic and complex conditions. It becomes even more critical from a health system sustainability perspective when the treatment is a high-cost therapy.
- In the case of specialty medications where the diseases are more serious, non-adherence heightens cost and increases risk, potentially leading to disease progression or increased morbidity. Non-adherence may also result in wastage of the medication itself, which, in the case of a specialty medication, represents a very significant cost.

Patients with chronic and devastating diseases can live in fear, anxiety and uncertainty. This emotional roller coaster takes its toll, impacting personal joy, relationships, and the ability to cope. For the patient, the journey towards new specialty treatment options can help make the diagnosis less overwhelming. A multidisciplinary healthcare team is often needed to treat patients taking specialty medications due to their complex needs and symptoms.

Appreciating the considerable quality-of-life improvements specialty medications can offer, it may be surprising to learn that, according to Canada's Patented Medicines Pricing Review Board (PMPRB), in 2017, less than 1% of Canadians were taking these medications.⁸

While there is sensitivity around the higher cost of these drugs, the overall cost of any medication also encompasses downstream costs of compromised adherence, and morbidity or mortality resulting from non-optimized care.

Acknowledging the differences between Canadian and American healthcare delivery models, the annual downstream costs of non-optimized drug therapy in the United States in 2017 were considerable, estimated at \$528.4 billion USD and 275,689 deaths. These estimates include costs associated with the use of other medical resources such as physician and ER visits, additional medications, hospitalizations, and long-term care stays.⁹



Drug therapy problems are a key driver of medical resource utilization. One study showed that 12% of Emergency Room visits at a large Canadian hospital were due to drug related problems and most of these visits were preventable.¹⁰ As medication experts, pharmacists are well-positioned to manage drug therapy and reduce the cascading costs associated with non-optimized treatments. Pharmacists' role is vital for all patients with chronic and complex conditions. It becomes even more critical from a health system sustainability perspective when the treatment is a high-cost therapy.¹¹

⁸ <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380&lang=en#a7> accessed 30 Aug 2018

⁹ Cost of Prescription Drug-Related Morbidity and Mortality, Jonathan H. Watanabe, Terry McInnis, Jan D. Hirsch, Annals of Pharmacotherapy 2018, Vol 52(9) 829-837

¹⁰ Zed PJ, Abu-Laban RB, Balen RM, et al. Incidence, severity and preventability of medication-related visits to the emergency department: a prospective study. *CMAJ*. 2008;178(12):1563-1569.

¹¹ Cost of Prescription Drug-Related Morbidity and Mortality, Jonathan H. Watanabe, Terry McInnis, Jan D. Hirsch, Annals of Pharmacotherapy 2018, Vol 52(9) 829-837



Each specialty medication has specific requirements based on several criteria, and there are many patient considerations relevant to therapy optimization (**see Appendix A**). Once treatment is prescribed, the patient typically enrolls in an industry-funded patient support program (PSP) with which the pharmacy interfaces directly. The PSP provides support and assistance to the patient during their transition to treatment.

The role of the pharmacy through the PSP is essential, not only because each medication has specific instructions, but also to educate and involve the patient in therapy optimization.

Promoting Adherence to High-Cost Drug Therapy

Adherence to medication is another notable example of the support required by patients to optimize outcomes. Non-adherence is a common problem, with one study estimating that 29% (range 3% to 64%) of patients did not take the correct number of doses as prescribed.¹²

According to the 2003 World Health Organization examination of *Adherence to Long Term Therapies*, “the consequences of poor adherence to long-term therapies are poor health outcomes and increased healthcare costs.”¹³ It is estimated that, in Canada, between 5.4 percent and 6.5 percent of hospital admissions are the result of non-adherence, resulting in annual costs as high as \$1.6 billion.¹⁴

In the case of specialty medications where the diseases are more serious, non-adherence heightens cost and increases risk, potentially leading to disease progression or increased morbidity. Non-adherence may also result in wastage of the medication itself, which, in the case of a specialty medication, represents a very significant cost. For these reasons pharmacists take extra care to counsel these patients on the importance of remaining adherent to therapy and will work with patients to develop strategies that help them stay adherent.

Evidence demonstrates adherence to specialty medications improves when patients receive the services required to support proper use.

Non-adherence drivers include:

- **Fear of experiencing side effects**
- **Complexity of administration**
- **Fear of needles**
- **Lack of understanding of the disease and/or therapy**
- **Drug costs**

¹² Claxton AJ, Cramer J, Pierce C. A systematic review of the associations between dose regimens and medication compliance. Clin Ther. 2001;23(8):1296-1310.

¹³ https://www.who.int/chp/knowledge/publications/adherence_full_report.pdf Adherence to Long-term Therapies, Evidence for Action, WHO

¹⁴ Casey B. Pharmacare now: Prescription medicine coverage for all Canadians. Report of the Standing Committee on Health. House of Commons Canada. Ottawa, ON; April 2018, page 122 accessible at <https://www.ourcommons.ca/Content/Committee/421/HESA/Reports/RP9762464/hesarp14/hesarp14-e.pdf>



Financial Burden of Specialty Medications

Critical to this discussion is the role the financial burden plays in specialty medication adherence. For many patients, out-of-pocket costs for specialty medications are considerably higher than traditional medications. Cost is especially a problem for specialty medicines given that a 20% co-payment, while manageable for most drugs, is not manageable for specialty medications because of their high cost. This cost issue is one of the main reasons reimbursement navigation and patient assistance is such an important part of specialty pharmacy: to ensure patients access their medication on time and to ensure they adhere to their therapy without interruption due to financial barriers.

A Canadian study based on 2007 data found 1 in 10 Canadians is non-adherent to medications due to out-of-pocket costs. Those with low incomes, those who are ill, and those without insurance are most likely to be non-adherent. Another study found 1 in 3 Canadians does not fill prescriptions at all.¹⁵

Increasing engagement and education surrounding drug adherence will result in a reduction of many additional costs that benefits plans and employees may be absorbing, as well as fewer hospital visits and slower disease progression.

Even if better coverage for these life-saving and life-altering therapies is offered, we will not realize their full value and benefit without ensuring that patients can access and *adhere* to these medications. Pharmacists play a pivotal role in ensuring adherence through patient education, and by helping patients navigate the financial burden associated with specialty medications.

If a comprehensive system is not created to address adherence, advances in biomedical technology will fail to reach their potential to reduce the burden of chronic illness.¹⁶

Pharmacy Support Improves Patient Adherence

There is abundant evidence demonstrating that when pharmacies work with patients to focus on specialty medications, adherence is managed by as much as 15% better than when pharmacy services are absent.^{17,18}

Non-adherence to drug therapy comes at a high cost to the Canadian healthcare system. Non-adherence to medications costs the Canadian healthcare system \$4 billion annually and accounts for 5% of hospital admissions and 5% of physician visits annually.¹⁹ This issue is more significant in the case of specialty medications, since this drug therapy actually alters the course of serious and complex diseases. Patients may suffer loss of productivity and even face significant risks of morbidity if they do not persist with treatment or are non-adherent.²⁰

¹⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3281154/> The effect of cost on adherence to prescription medications in Canada accessed Oct 21, 2018

¹⁶ <https://www.drugstorenews.com/pharmacy/specialty-pharmacies-toe-the-line-between-access-cost-and-outcomes/> accessed Oct 21, 2018

¹⁷ <https://www.ncbi.nlm.nih.gov/pubmed/20652656/>

¹⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5477418/#CR40>

¹⁹ <https://www.benefitscanada.com/benefits/health-benefits/non-adherence-costs-employers-58070>

²⁰ <https://www.benefitscanada.com/benefits/health-benefits/non-adherence-costs-employers-58070>



An essential role for pharmacy is to continually engage patients in managing their disease and its treatment, so patients understand the journey, actively participate, and remain adherent.

Reimbursement Navigation Assistance

For a patient already anxious about a diagnosis or the worsening of a condition, paying for and receiving reimbursement for a costly, newly-prescribed treatment can compound anxiety.

Pharmacies frequently work with patients by taking on the critical yet often unmet need for navigating reimbursement. Pharmacies assist with navigating the reimbursement process to ensure patients can begin their therapy as soon as possible and maintain the treatment as prescribed.

The role of pharmacies in reimbursement navigation is key to initiating the kind of prompt, uninterrupted care conducive to mitigating disease progression. Pharmacy's support in reimbursement navigation and financial assistance continues *throughout* therapy, not just when therapy is initiated. These supports are critical for timely access to therapy, and also to ensure patients persist on their treatment.

For patients taking specialty medications where out-of-pocket costs are high, reimbursement navigation assistance from pharmacies is vital to reduce the risks associated with non-adherence or treatment abandonment.

| Patient Need | Consequence if Need Unmet | Pharmacy Service to Address Need | Time Required (mins) |
|-------------------------------|---|----------------------------------|----------------------|
| Who is going to pay for drug? | Patients are not familiar with options and who to contact, how to navigate Risks: <ul style="list-style-type: none">• Patient stress• Therapy delays/abandonment• Selection of alternate sub-optimal therapy• Disease progression | Reimbursement navigation | 30-120 |

Reducing Medication Waste

Medication waste is unfortunate and costly, especially where specialty medications are concerned. Naturally, pharmacies work hard to minimize losses due to improper handling and shipping of the medications because they are so expensive. Great care is taken by all parts of the supply chain to reduce the possibility of damage and ensure that proper temperatures are maintained at all times in the journey from manufacturer to distributor to pharmacy to patient. We have already seen that additional time is spent preparing medications for shipping and that more expensive packaging materials are frequently used.



However, inappropriate use is another scenario which leads to medication wastage. Inappropriate use may occur when the patient does not understand how to take the medication to receive the desired therapeutic effect. For example, some specialty medications may be self-injected by the patient. For these types of medications, each patient will receive 30 – 50 minutes of training until they have mastered the proper technique.²¹

Care Coordination

The unique requirements associated with specialty medications far exceed what is required to manage traditional medications. What is more, failure to meet these requirements jeopardizes the investments made by public and private payors.

If patients with complex diseases, and the healthcare infrastructure that supports them, are to realize the full benefit of specialty medications, then all services that underpin the patient journey must be supported.

By supporting the services offered to patients taking specialty medications, benefits accrue to the entire system. Treatment value is optimized, and the downstream costs related to treatment failure are minimized.

Funding

When glancing ahead, we can already see specialty medications dominate the drug pipeline of the future.²² Most of the increase in drug spending will result from utilization in this category.²³

The patient support programs that assist patients taking specialty medications have been manufacturer-funded since their inception. A recent study of Innovative Medicines Canada (IMC) members found that industry investment is significant: \$900 million in 2016, up from \$560 million in 2015.²⁴

The effort to maximize the efficiency of healthcare dollars without compromising care is underway in the private and public sectors. Canada's healthcare model is transforming to provide better care, better health, and better value when it comes to spending on drugs.

To ensure the principles of value and responsibility remain closely associated with these high-cost therapies, funding pharmacy services for high-cost drug therapies will help support the efficient use of resources for patients taking specialty medications.

²¹ Neighbourhood Pharmacy Association of Canada, survey of members, August 2018

²² Express Scripts Canada Drug Trend Report Executive Summary, 2017

²³ <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380&lang=en#a7>

²⁴ http://innovativemedicines.ca/wp-content/uploads/2017/10/20171030_EY-REPORT_IMC_FINAL.pdf





POLICY AND PROGRAM RECOMMENDATIONS

- We propose a joint, ongoing strategy involving the public and private sector, to investigate, assess, and advance the potential of these medications to improve patient and health system outcomes.
- We emphasize that pharmacies' role in education, adherence, financial support, handling and monitoring, as well as medication waste reduction, is vital when evaluating reimbursement and funding for specialty pharmacy services.
- We believe increasing the engagement of payors and policymakers in the area of specialty medications will improve the administration of this drug therapy.
- Including our sector's expertise in the design of a funding model will achieve the benefits that a coordinated approach to specialty medications can deliver.
- Reviewing pharmacy's data on specialty medications will facilitate an appreciation of the clinical and cost effectiveness of specialty medications.

1. While there is definite value in gaining an enhanced understanding of the role of specialty medications in the lives of patients and the healthcare system, the story does not end with the information included in this report. We propose a joint and ongoing strategy, involving the public and private sector, to continue investigating, assessing, and advancing the potential of these medications to improve patient health and health system outcomes.
2. When evaluating reimbursement and funding for specialty pharmacy services and products, the factors identified in this report should be considered. In particular, the services pharmacy provides in education, adherence, financial support, handling and monitoring, and medication waste reduction is vital. Pharmacy plays an instrumental role in optimizing specialty medications for the patient, the payor, and the healthcare system.
3. The findings of this report strongly indicate that increasing the engagement of payors, and policymakers in the area of specialty medications will help improve the delivery and administration of this high-cost drug therapy.
4. To ensure pharmacy continues to play a vital role in efficiently delivering specialty medications, adequate and sustainable funding is recommended. In evaluating sustainable funding for these complex medications and the services required to support them correctly, we recommend pharmacy be viewed as a pivotal contributor to these discussions. Including our sector's expertise in the design and implementation of a new model will help achieve the full range of benefits that a coordinated approach to specialty medications can deliver.
5. To pursue a thorough understanding of specialty medications, their requirements and how to achieve optimal outcomes, the importance of reviewing pharmacy data is pivotal. Examining and considering the data will facilitate a more complete appreciation of the clinical *and* cost effectiveness of this approach to drug therapy.



Appendix A: Pharmacy Services for Patients Taking Specialty Medications



| Patient Need | Consequence if Need Unmet | Pharmacy Service to Address Need | Time (mins) |
|---|---|---|-------------|
| Adherence | Therapeutic outcome will be sub-optimal Disease progression | Patient Education/engagement Adherence support | 5-30 |
| Injection Training | Additional cost for healthcare provider to inject Treatment delays or abandonment Disease progression | Patient Education | 30-50 |
| Other assistance | Compromised disease and/or therapy understanding Disengagement Disease progression | Patient Education | 15-60 |
| Onboarding | Failure to assess Pre-treatment vaccine status, drug interactions Drug-disease interactions Allergies Co-morbidities Lab work schedules Risk of inappropriate drug use | Medication Management, confirm appropriateness of therapy | 10-30 |
| Side Effects | Patient may stop drug early or unnecessarily Disease progression | Education and side effects management | 5-60 |
| Pre and Post Care support | Mandatory lab work missed leading to delayed treatment (and potential drug waste) Hospitalizations Additional health issues Failure to change therapy where indicated | Medication Management, ongoing patient contact | 10-20 |
| Infusion Booking | Lower adherence Compromised effect of therapy (if infusion timing protocol unmet) Dosing issues Therapy drop-offs Disease progression | Care coordination to treatment schedule | 10-45 |
| Blood work | Dosing issues Inappropriate therapy starts (e.g. incomplete washout) Failure to adjust therapy where indicated | Care coordination, align treatment to lab results | 10-30 |
| Pharmacogenetic or companion diagnostic testing | Inappropriate therapy or appropriate therapy not considered Lower effectiveness, disease progression Drug waste | Care coordination | 10 |
| Who is going to pay for drug? | Patients are not familiar with options and who to contact, how to navigate Risks: <ul style="list-style-type: none"> • Patient stress • Therapy delays/abandonment • Selection of alternate sub-optimal therapy • Disease progression | Reimbursement navigation | 30-120 |
| Product needs to arrive at specific place for administration | No drug where and when needed for patient <ul style="list-style-type: none"> • inconvenience; therapy abandonment • missed or delayed dose • dosing issues Risk of drug waste Disease progression | Packaging, handling, shipping | 10-15 |



| Patient Need | Consequence if Need Unmet | Pharmacy Service to Address Need | Time (mins) |
|---|---|---|-------------|
| Product needs refrigeration – cold chain | Product integrity may be compromised Possible negative impact on therapy outcome Significant risk of drug waste | Packaging, handling and temperature controlled and monitored shipping | 5-15 |
| Simplified packaging to improve compliance | Limitations to continue self-care Compromised adherence Dosing and treatment issues Disease progression | Compliance packaging, handling | 10-30 |
| Handling dangerous drugs, disposal | Safety risk to patient, caregiver and healthcare provider (e.g. cytotoxic drugs) | Packaging, handling, operating procedures, education | 15-45 |



Appendix B:

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