2020

REPORT ON THE 2020 CANADIAN PRIVATE PAYER PRODUCT LISTING AGREEMENT STUDY

connex

PDCI MARKET ACCESS

H3 CONSULTING

1. CONTENTS

EXECUTIVE SUMMARY

This report on private payer Product Listing Agreements (PLAs) is a collaborative effort between PDCI Market Access Inc., Connex Health Consulting and H3 Consulting. It updates and significantly expands the ground-breaking 2015 PDCI/H3 report and was driven by the ongoing presence of PLAs in the private payer marketplace. This year, a more extensive online survey and eight hour-long qualitative interviews were conducted to probe the experiences and perspectives of private payers and drug manufacturers.

Both private payers and drug manufacturers reported that there have been a significantly greater number of PLAs negotiated in the Canadian market in recent years. Several important changes are highlighted in the blue text box.

Both payers and manufacturers are realizing that PLAs have become the new way of doing business. For certain drug classes (e.g. biologics) they are now more frequently considered a condition of listing. Both sides have invested in private market PLA strategy, resources and negotiation expertise.[1] This is demonstrated by the increasing use of health economics analysis as well as larger in-house negotiation teams. While price continues to be the most common target in PLA negotiations, more agreements are moving towards consideration of total cost, budget impact and overall value. This indicates future agreements will have a greater emphasis on economic value.

Interest in private PLAs is expected to remain strong over the next three years, however several broad market developments may change the dynamics and content of these agreements.

KEY TAKEAWAYS

- **Private PLA activity has significantly increased since 2015.**
  - One large insurer's communication indicates PLAs save its clients tens of millions of dollars annually in drug costs.
- **Reducing product cost and/or budget impact is the primary motivator for private payers to pursue PLAs.**
- **Manufacturers are motivated to negotiate private PLAs primarily to secure reimbursement for high-cost products and to avoid managed access mechanisms.**
- **Manufacturers are more interested in PLAs for products that cost more than $50,000 annually, while payers target drugs priced more than $10,000 per year.**
- **PLAs for certain high-cost drug classes, especially biologics, are frequently seen as a condition of listing.**
- **Agreements based on health outcomes are rare in the private market, despite interest among payers and manufacturers.**
- **Both manufacturers and payers expressed positive attitudes about their PLA negotiation experiences and outcomes.**

[1] Many manufacturers and some smaller insurers still have no direct experience with private PLAs.

Common Ground and Canyons

The perspectives of the two industries largely align on three areas of negotiation, which have facilitated more PLA activity:

- Demonstrating cost-effectiveness,
- Managing products with uncertain or variable patient cost, and
- New indications, biologics, oncolytics and drugs costing more than $20,000.

Manufacturers and payers also have different motivations and goals. Controlling product price, cost and budget impact are the primary motivators for private payers. In contrast, manufacturers seek to improve reimbursement outcomes, especially for high-cost products, for example, by mitigating effects of managed access mechanisms. Different leverage between payers and manufacturers means negotiations are likely to be more difficult with biosimilars, drugs for rare diseases (DRDs),[2] drugs costing less than $10,000 and first- and third-in-class products. Larger payers are beginning to move beyond high-priced specialty drugs and require negotiations for lower-priced new drugs, even below $10,000 in annual cost. In contrast, manufacturers express no interest in negotiating prices for drugs costing less than $10,000.

PLAs can't succeed without strong operational relationships. However, both industries expressed concern that drug manufacturers' global leaders sometimes consider private PLAs to be less important than a pan-Canadian Pharmaceutical Alliance (pCPA) negotiation, if a private market agreement is necessary at all. While the private drug insurance market is now the largest payer in Canada, it is still less attractive to manufacturers due to the added cost and inefficiency of separate negotiations. Some of this incremental cost will be mitigated if PBMs step in to aggregate the business of smaller insurers and deliver scale comparable to the four or five largest carriers.

Health outcomes-based PLAs retain interest, but value-based PLAs have arrived

PLAs based on health outcomes are an aspiration for both payers and manufacturers. Such targets should help assure appropriate prescribing and termination of covered products when therapy is no longer effective, optimizing and ensuring value for both payers and patients. However, private market stakeholders have limited capability, resources or infrastructure to negotiate and administer PLAs based on health outcomes. Already the pCPA is believed to have concluded some health outcomes-based agreements which include systems to implement and track these deals. For private payers, the intermediate step is value-based agreements (VBAs). While VBAs have no set definition, they seek a closer link between price and the benefits brought to patients and payers.

Given mutual interest, solid operational relationships, and manufacturer experience with the pCPA, manufacturers and private payers may be motivated to jointly develop a framework for VBAs and health-outcomes focused PLAs.

Important market developments

Private payer PLAs still face important challenges in the short and medium term. The dominant uncertainty is PMPRB reform which will decrease list prices for patented medicines in Canada. These changes will blunt growth in new

[2] The federal government again indicated it will develop a national DRD strategy in the 2020 Speech from the Throne.

private PLAs and may cause review or negation of older PLAs due to significantly shrinking manufacturer profit margins or new price reductions that are below previously negotiated levels.

Other developments to watch include:

- Work on a new national strategy for DRDs may transfer all or almost of the cost for these drugs to the federal government.
- Reaching decisions about the breadth, cost and timing to implement a national formulary will be difficult.[3] Assuming the formulary becomes a minimum standard for private plans, their larger current formularies and their appetite for regulation in this area present other challenges.
- The Canadian Life and Health Insurance Association Inc (CLHIA) continues to advocate the integration of private insurers with the pCPA for price negotiation of new patented drugs.
- Oncology is by far the largest pipeline class. High-cost orally-administered cancer medications often fall first into private plans and remain there exclusively in the four provinces that do not cover these drugs except on individual consideration.
- The prices set by manufacturers for some innovative technologies (e.g. some DRDs and new gene and cell therapies) are so high that the gap in perceived value and affordability may be too great for payers and manufacturers to close through negotiation.
- The steady success of the pCPA model has also created pressure for insurers and PBMs to achieve similar savings. As the pCPA evolves, expect the private market to follow.

Now is certainly a fascinating and also challenging time in reimbursement. As investment in innovation grows and payer budgets continue to be strained, it is incumbent on all stakeholders to work together to ensure timely and affordable access to care for patients. PLAs are one mechanism used to achieve this goal. It is significant that the number of agreements has grown since 2015 and it appears highly likely this growth will continue.

The last words

We want to thank all the manufacturers and payers who gave their time to complete our survey and especially those who agreed to be interviewed, contributing even more of their experience and insight to this research.

Suggested citation

Connex Health, H3 Consulting, PDCI Market Access, 2020. *Report on the 2020 Canadian Private Payer Product Listing Agreement Study.*

Readers are welcome to cite any information in this report with attribution to Connex, H3 Consulting and PDCI Market Access.

[3] The federal government again indicated in the 2020 Speech from the Throne that it would develop a national formulary that would presumably include all public and private drug plans.

INTRODUCTION

Access to medicines in Canada is facilitated through a combination of payers including public and private drug insurance plans and cash paying customers. The Conference Board of Canada recently estimated that approximately 34.3 million Canadians (90%) are eligible for some form of prescription drug coverage, with about 22.5 million Canadians (60%) enrolled in private drug plans.[1]

The drug benefits landscape in Canada has evolved rapidly in recent years, as fundamental advances in health science and medical technologies have changed the mix of innovative medicines available. In the past, small-molecule "blockbuster" drugs developed to treat common conditions in large numbers of patients were seen as the key drivers of drug spending.

Since 2015, several private drug insurance industry stakeholders have responded to these challenges by investing in their capabilities to more actively manage expenditures.

Today, an innovation frameshift has changed how countless medical conditions are treated. Many new medicines can cure or substantially alter the natural history of disease for many previously life-threatening or serious, incurable conditions. However, this innovation has brought with it sustainability and affordability challenges for public and private payers.

Private drug plans are big business and an essential source of drug funding and access in Canada. Private prescription drug insurance spending was estimated at $12.7 billion in 2019 and has exceeded spending by provincial governments since 2017.[2] However, private drug plans have historically been an afterthought to achieving public reimbursement by drug manufacturers because only a minority of private formularies are actively managed.[3] This is changing.

By 2018, specialty drugs – including drugs for rare diseases, large-molecule biologic products, and others designed to treat highly specialized conditions – accounted for 33% of Canadian drug spending despite representing only 2% of drug claims.[4]

Over the last decade, several private drug insurance industry stakeholders responded to these challenges by investing in their capabilities to more actively manage expenditures. While some established programs which include formal health technology assessments, others rely on standard cost-containment strategies such as mandatory generic substitution, prior authorization, formulary-based plans, step therapy, or lifetime or annual plan maximums. A decade ago, PLAs were only beginning to become common in public drug plans. Today they've become an important element in private reimbursement conversations as well.

PLAs are negotiated contracts which confidentially determine the specific terms under which the payer agrees to reimburse a drug. They typically involve a lower price, cost or budget impact. Agreements can be used to help patients access a new drug, while managing risks to the payer and plan sponsor regarding any uncertainties, such as how a new drug may be used, or its effectiveness in the real-world.

In Canada, PLAs have been a feature of public drug plan market access for about 15 years,[5] however they only became an expected component of achieving public market access after 2010, when several Canadian jurisdictions created the pan-Canadian Pharmaceutical Alliance (pCPA) to leverage their combined negotiating power. As of September 28, 2020, the pCPA had completed 381 negotiations under its brand initiative, 86% of which concluded with a Letter of Intent. Twenty-eight more drugs were under consideration and 77 negotiations were not pursued.[6] The pCPA's brand initiative does not include private payers, but its other initiatives have set many generic drug prices and have mandated transparency for biosimilar prices that apply to all payers.

Private payers have different capacity, approaches and expectations for PLAs, and were slower to take interest compared with public payers. Several private payers independently pursue their own PLAs, separately from the pCPA.

The pCPA has grown its capacity, becoming more sophisticated, formalized and it has improved transparency in its processes. Private payers have not consolidated or coordinated their approach to PLAs. They have different capacity, approaches and expectations for PLAs, and were slower to take interest compared with the public payers. Today, however, several private payers independently pursue their own PLAs, separately from the pCPA.

Sun Life appears to have been the first insurer to negotiate a private market PLA in 2014.[7] In September 2015, Manulife introduced its DrugWatch™ program to monitor, screen, evaluate and make listing decisions for new high cost and/or high-volume drugs.[8] Other private payers have since implemented programs with similar objectives, including Canada Life's (formerly Great-West Life) SMART drug plan and Sun Life's Drug Risk Management Program. These programs use proprietary criteria to consider reimbursement of new drugs. These three insurers control a majority of the private health benefits market.

In 2015, H3 Consulting and PDCI surveyed manufacturers and payers about their interest and experience with private PLAs. Four reports addressed the prevalence, objectives and content of private PLAs in Canada. At that time: [10-13]

- 37% of manufacturer respondents and 50% of private payer respondents reported having experience negotiating a private PLA;
- 42% of manufacturer respondents and one quarter of private payer respondents reported no interest in negotiating a private PLA; and
- 21% and 25% of manufacturers and private payers, respectively, reported interest but no prior experience negotiating private PLAs.

This report addresses the landscape of private PLAs in 2020, including the frequency, type, goals and impacts of PLAs negotiated between drug manufacturers and private insurers or pharmacy benefit managers (PBMs). Since 2015, much has changed in the private PLA landscape. More change is likely, driven by this market segment as well as by public payers and the broader pharmaceutical policy arena within which PLAs operate.

STUDY OBJECTIVES

In 2020, the research team consisting of Connex Health, H3 Consulting and PDCI updated and expanded the 2015 Private PLA Study. We engaged manufacturers and private payers in both quantitative (survey) and qualitative (interview) research to better understand the current landscape for private payer PLAs. The research team also sought stakeholders' perceptions on what the future holds for private PLAs considering anticipated drug policy and market changes.

Our study objectives were:

1. To understand the current state of PLAs in 2020, including:
    a. The prevalence of PLAs among the payer and manufacturer survey respondents;
    b. Mechanics of the negotiation process;
    c. Types of products and agreements negotiated;
    d. The similarities and differences in manufacturer and payer experiences, perspectives, motivations and satisfaction concerning PLAs;

2. To understand if and how the landscape has evolved since 2015; and
3. To gather manufacturer and payer perspectives on the future of private payer PLAs.

STUDY METHODOLOGY

Between March 2020 and August 2020, the research team completed two phases of research.

In Phase 1, an electronic survey was open between April 16 and May 15, 2020. Survey respondents were recruited through PDCI's TargetPharma email newsletter, and via other social media channels. Interested participants received a SurveyMonkey® link to the manufacturer or payer version of the survey. All participants were known to the research team. Manufacturer representatives were typically senior market access professionals responsible for private reimbursement of their company's products. Payer representatives were employed by insurance companies or pharmacy benefit managers and were responsible for drug evaluation and/or listing decisions. Participants were sent the anonymized raw survey data in appreciation of their contribution to the study. Surveys were analyzed using a quantitative analysis method using Microsoft Excel® software.

Phase 2 used qualitative research (interviews) to explore individual perceptions and experiences with PLAs as well as each participant's history and the context of their roles and situations. Data and themes are rooted in the language used by participants. Qualitative research helps gain insight and complement quantitative approaches to achieve deeper understanding. Five manufacturer and three private payer interviews were conducted with a subset of survey respondents in July and August 2020. These exploratory interviews were semi-structured based on a prepared discussion guide and conducted using Microsoft Teams® conferencing technology. Each discussion was at least one hour in duration and included two members of the research team. The interview recordings were used to check researcher notes, to uncover important themes and to extract relevant quotes for this report. All participants were promised anonymity.

Data from the interviews were analyzed using a basic thematic analysis. This approach allowed systematic identification of themes that are present in the interview data. Inductive logic was used to allow themes to emerge from the data. The interviews were used to clarify and extend survey results and to identify new information and perspectives from a small, non-random subset of the survey respondents. Their views may or may not represent those of their peers but the research team felt the selected participants were very experienced, highly qualified and likely to represent a range of perspectives.

PHASE 1 SURVEY RESULTS

In phase 1, 17 manufacturers and six private payer representatives (from five insurers and one PBM) completed the survey.

EXPERIENCE WITH PLAs

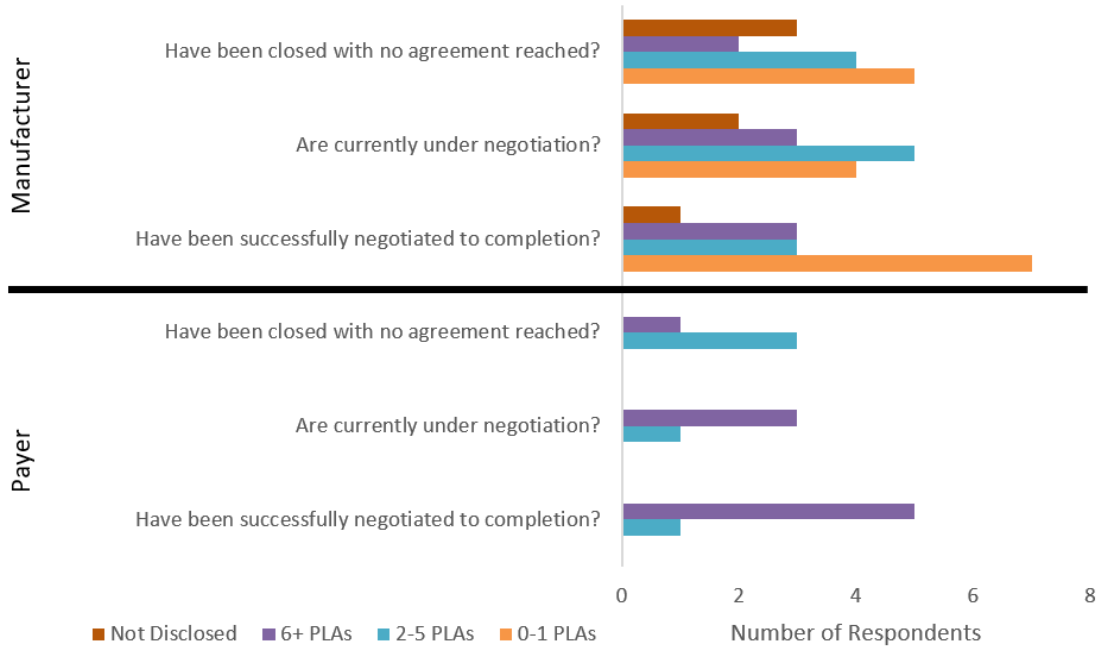
Fourteen of 17 manufacturer respondents reported experience negotiating private payer PLAs. All findings are based on these respondents. All six payer respondents, representing well over 50% of the group drug benefit market,[9] reported their company had experience negotiating PLAs.

Most manufacturers responded to questions related to the status of PLAs negotiated (n = 11) or under negotiation (n = 13).

- Completed negotiations: Three manufacturers reported successfully negotiating six or more PLAs to completion, three reported completing between two and five negotiations and six manufacturers reported completing only one negotiation.
- Under negotiation: Three manufacturers reported having six or more agreements currently in negotiation. Five reported between two and five negotiations underway. One reported having two negotiations in progress.
- Closed Negotiations: One manufacturer reported experience negotiating, but no negotiations had been successfully completed. Most manufacturers (n = 11) reported that they have closed at least one negotiation without an agreement.

Five payer respondents reported having successfully completed six or more PLAs. Four reported that PLAs are currently under negotiation and three payers reported six or more ongoing PLA negotiations. Four private payers reported between 2 and 5 negotiations had been closed without agreement and one payer reported at least six negotiations with no agreement reached.

Figure 1. Status of PLA Negotiations – Manufacturers and Payers



Private payers reported having a broad range of experience negotiating with many different manufacturers. Four payers reported negotiating with more than 10 different manufacturers. One payer reported only negotiating with one manufacturer, and one payer did not disclose this information.

Based on survey responses from both manufacturers and payers, more negotiations are successful than are not and the appetite for PLAs continues to be relatively strong. Experience is growing among both groups.

Manufacturers similarly reported a broad range of experience negotiating with different payers. Of the 12 manufacturers who responded to this question, three reported having negotiated with only one payer, one manufacturer reported having negotiated with 10 different payers and the others reported having negotiated with between two and nine different payers. On average, manufacturers had negotiated with four payers.

Based on survey responses from both manufacturers and payers, more negotiations were successful than are not and the appetite for PLAs continues to be strong. Experience is growing among both groups.

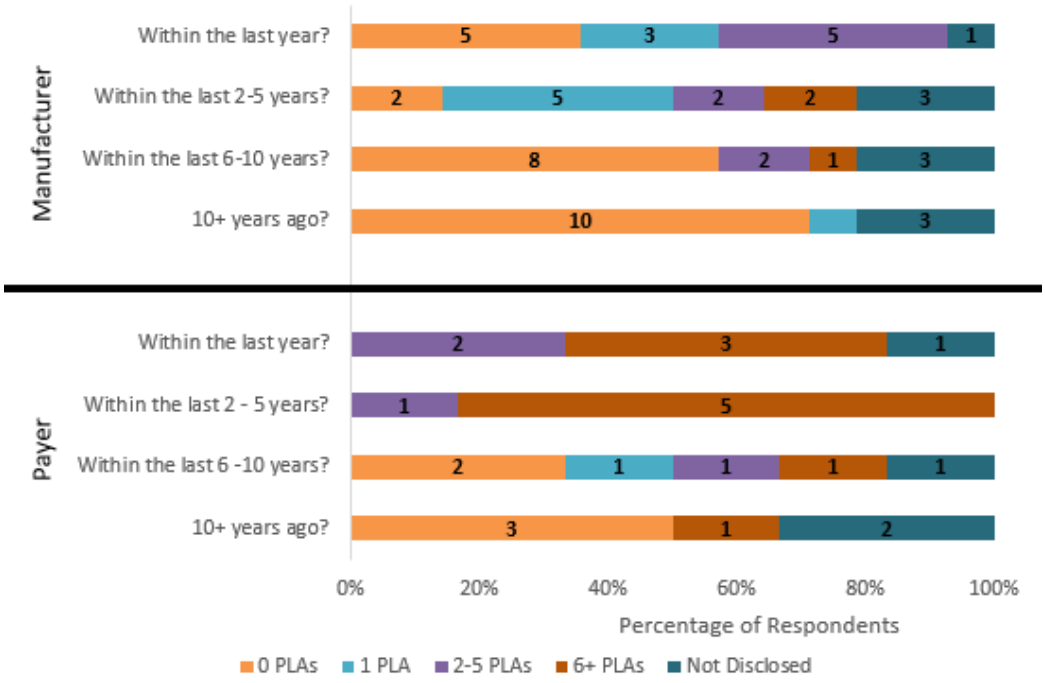
NUMBER AND FREQUENCY OF PLAS

Unlike the pCPA, whom reports on the number and status of PLAs monthly, the exact number of private PLAs is not known. The number of manufacturers who reported completed agreements over the last five years versus 6 to 10 years ago has increased (Figure 2). Eight manufacturers (61% of those who responded) reported negotiating one or

more PLAs in the last year and nine (82%) within the last 2 to 5 years. Five manufacturers reported no agreements in the last year versus two PLAs within the last 2 to 5 years.[4]

Payer respondents reported an increase in negotiated PLAs over the last five years. Within just the last year, five payers reported negotiating two or more PLAs. Three reported negotiating more than six PLAs. All six payer respondents reported that they had successfully negotiated two or more PLAs over the last 2 to 5 years.

Figure 2. Number PLAs negotiated over time – Manufacturers and Payers



Payers and manufacturers each reported the same number of PLAs negotiated in the last year and over the last 2 to 5 years (14 PLAs for manufacturers and six for payers). Comparing the last five years with those negotiated 6 to 10 years ago, there has been a significant increase in successful PLA negotiations. While the appetite for PLAs by private payers and manufacturers appears to be growing, annual counts of PLAs over the last decade would be necessary to confirm this impression.

[4] Note that one respondent did not disclose for the most recent year and three did not disclose for the other periods.

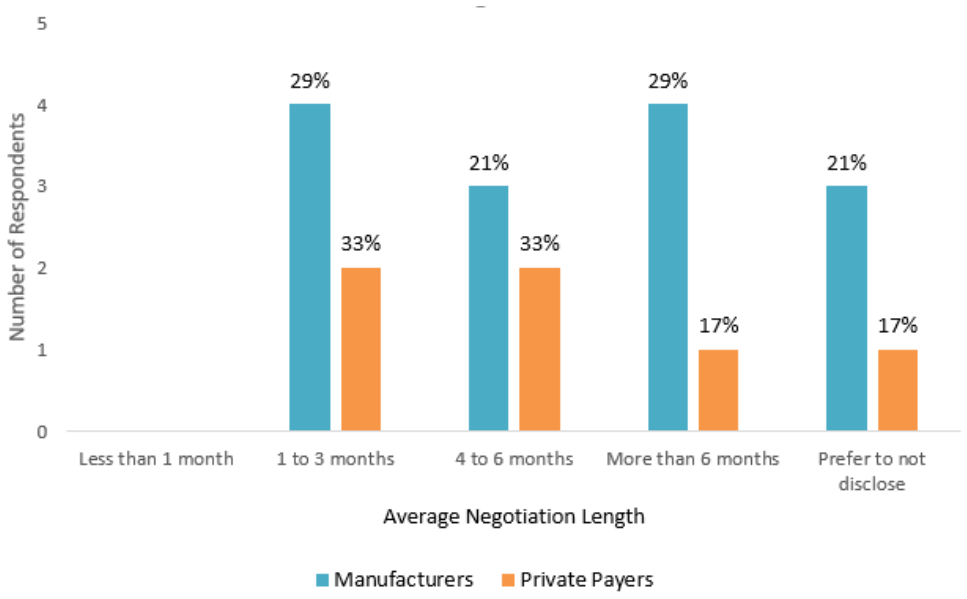
TIME REQUIRED TO COMPLETE NEGOTIATIONS

Eleven manufacturers reported the average time required to complete their PLA negotiations. These varied from one month to more than six months (Figure 3). An equal number of manufacturers (n = 4) responded that negotiations were completed in 1 to 3 months and more than six months, with 3 respondents reporting negotiations took between 4 to 6 months to complete.

The five payers who responded to this question reported an average negotiation time of six months or less. Two payers reported an average negotiation time of 1 to 3 months, two reported an average of 4 to 6 months and just one payer reported an average of greater than six months.

Manufacturers reported an equal percentage (36%) of negotiations completed in 1 to 3 months and more than six months. Payers generally reported an average negotiation time of six months or less.

Figure 3. Average PLA Negotiation Time in Canada – Manufacturers and Payers



Several factors were likely to have contributed to the time required to complete negotiations, including the complexity of the agreement, available resources, the internal approval process of both parties and the particular product.

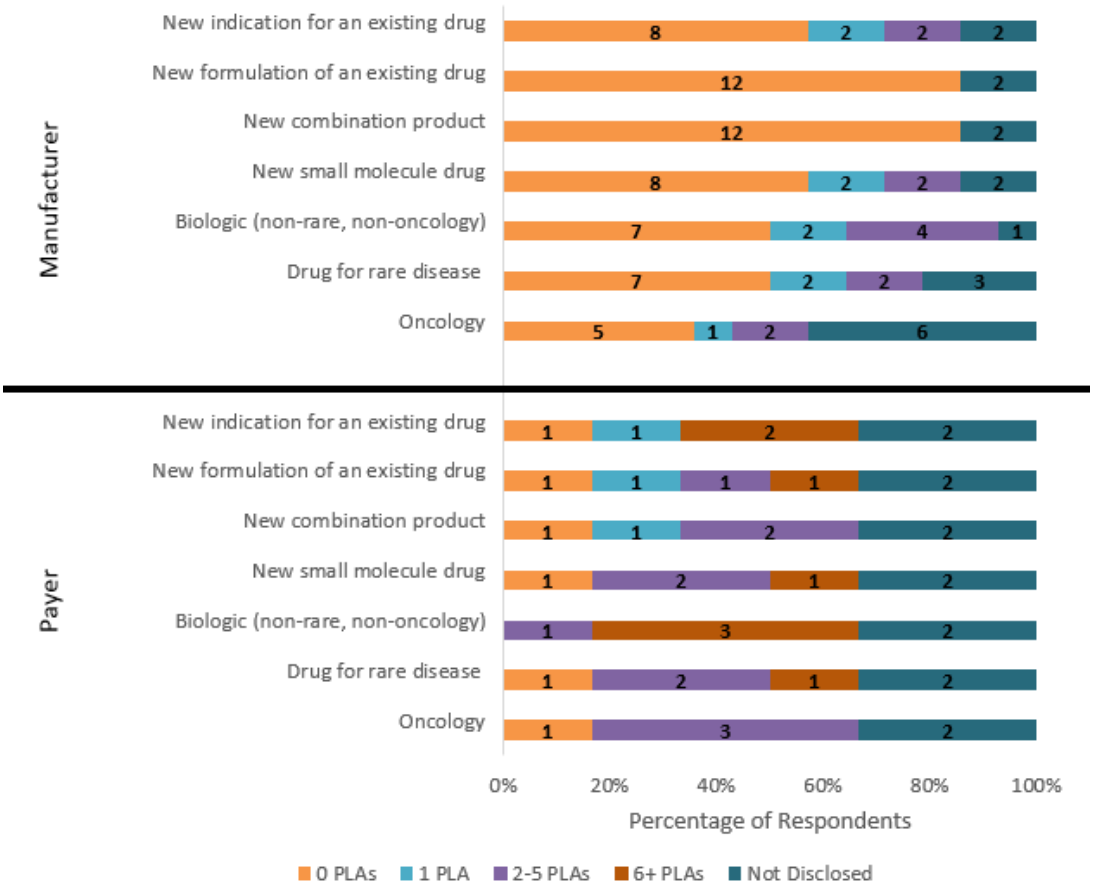
DRUGS SUBJECT TO PLAS

Manufacturers reported the highest number of PLAs for biologic drugs compared to other types of drugs (Figure 4). Six of 13 manufacturers who responded to this category reported at least one PLA for a biologic drug, including four manufacturers who reported completing 2 to 5 PLAs for a biologic drug. Five of six payers reported at least one PLA for a biologic drug.

In other categories, four of 11 manufacturers reported at least one PLA for a drug for rare disease, four for a new small molecule drug and/or a new indication for an existing drug. Three manufacturers of just eight responding to

this category reported at least one PLA for an oncology drug. No manufacturers reported PLAs for a new combination product or a new formulation of an existing drug. Half of the payer respondents (n = 3) reported at least one PLA negotiation in each category.

Figure 4. Types of products where a PLA was negotiated – Manufacturers and Payers

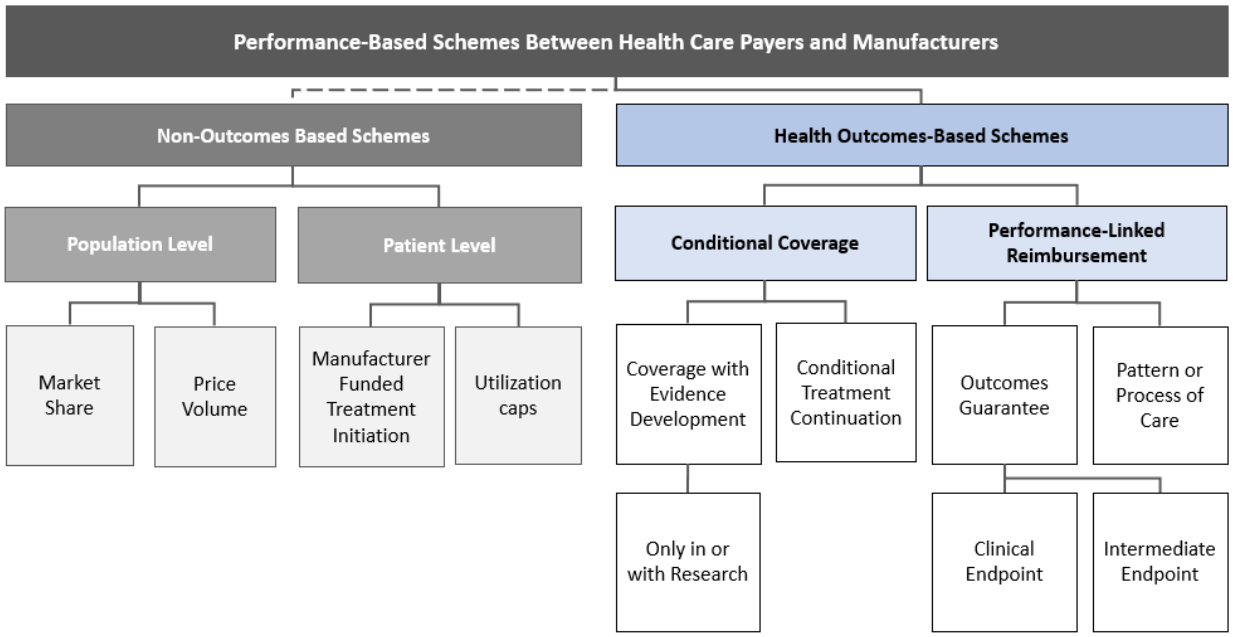


TYPES OF AGREEMENTS

PLAs can be in the form of price discounts, rebates, be based on volume, and/or be linked to health performance. Broadly, these fall under health outcomes-based agreements and non outcomes-based agreements. Figure 5 presents a taxonomy of possible formats and was included in the survey for participants to refer to. The following definitions are used in this report:

- Health outcomes-based program with performance-linked reimbursement: The discounted price is based on quantitative evaluation of patient outcomes within defined metrics.
- Health outcomes-based programs with conditional coverage: The discounted price is conditional on meeting defined patient outcomes.
- Non outcomes-based programs at the patient level: Price is discounted for each patient.
- Non outcomes-based programs at the population level: The discounted price is based on total eligible patient population.

Figure 5. Performance-Based Agreement Schemes[14]



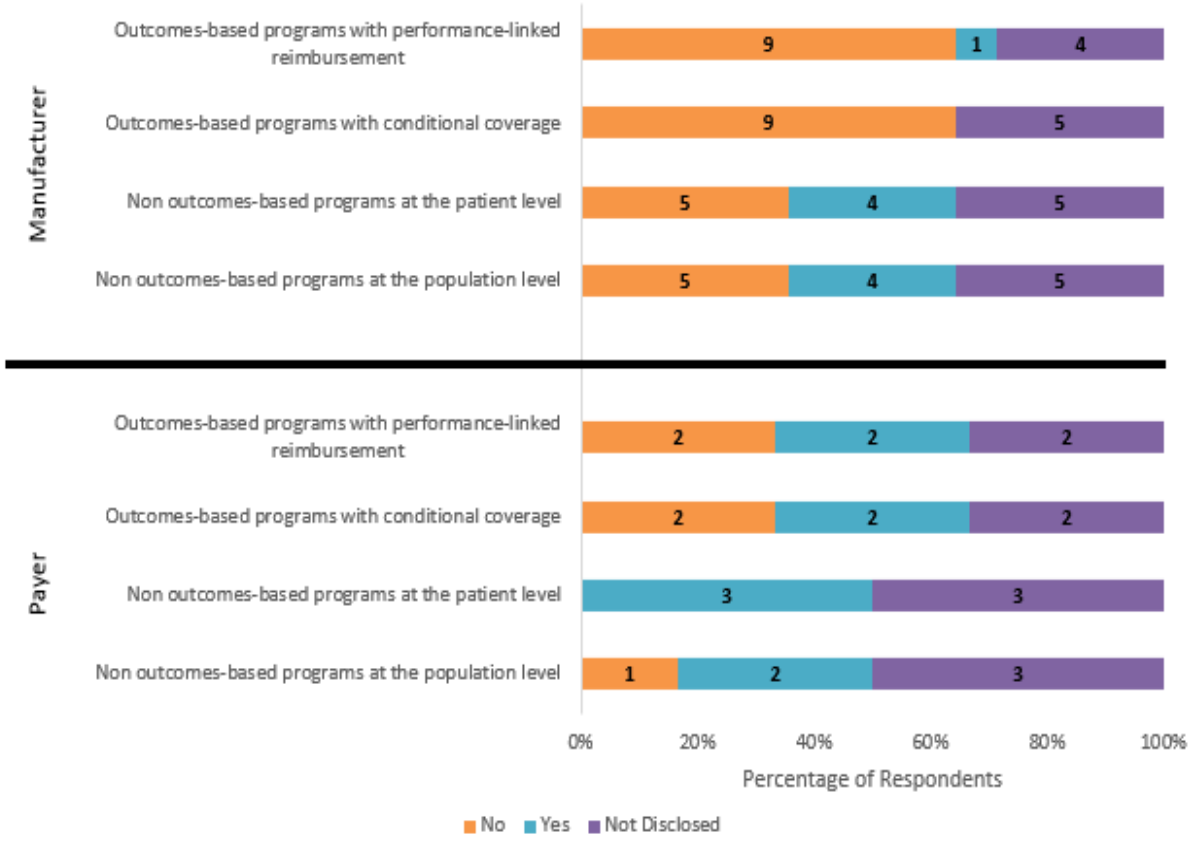
Ten of 15 manufacturers responded to our question about the types of PLAs. Only one manufacturer reported a PLA based on health with performance-linked reimbursement. No one reported a health outcomes-based agreement with conditional coverage. Four reported non-health outcomes-based PLAs at each of the patient and population levels (Figure 6).

Four of six payers responded to this question. Two payers reported health outcomes-based programs at each level (patient and population). Two payers reported the PLAs were linked to performance and two reported conditional coverage.[5] Three reported non-health outcomes-based agreements at the patient level. Two have PLAs at the population level.

It should be noted that there were few responses to this question and there may be some variation in how terms were defined by respondents.

[5] Results of the qualitative interviews conducted as part of this study suggested the definition of an "outcomes-based agreement" is not universally common to mean health outcomes. Therefore, these results should be interpreted with caution.

Figure 6. Types of PLAs negotiated – Manufacturers and Payers

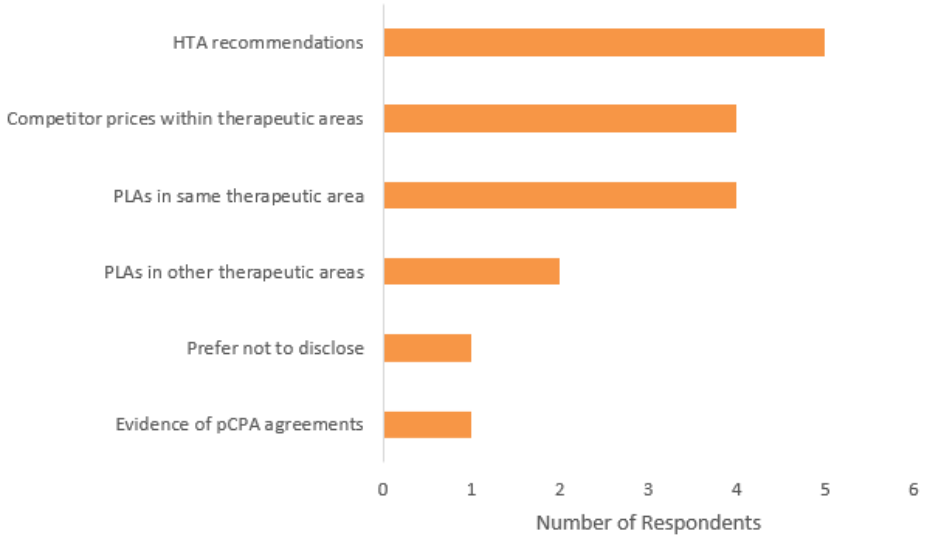


INFORMING GOALS OF PLAS

Five payers (of six) reported to rely on health technology assessment (HTA) to inform their PLA goals (Figure 7). Competitor prices within therapeutic areas and PLAs completed in the same therapeutic area were each noted by four payers as their main sources of information. There is limited capacity and information available for HTAs in the private sector. Many have stated they will consult or rely on HTAs done by the Canadian Agency for Drugs and Technologies in Health (CADTH) even though these use a health system perspective and so do not consider productivity-related information that is important to private payers.

This question was not asked of manufacturers.

Figure 7. Information used to inform goals of PLAs – Payers



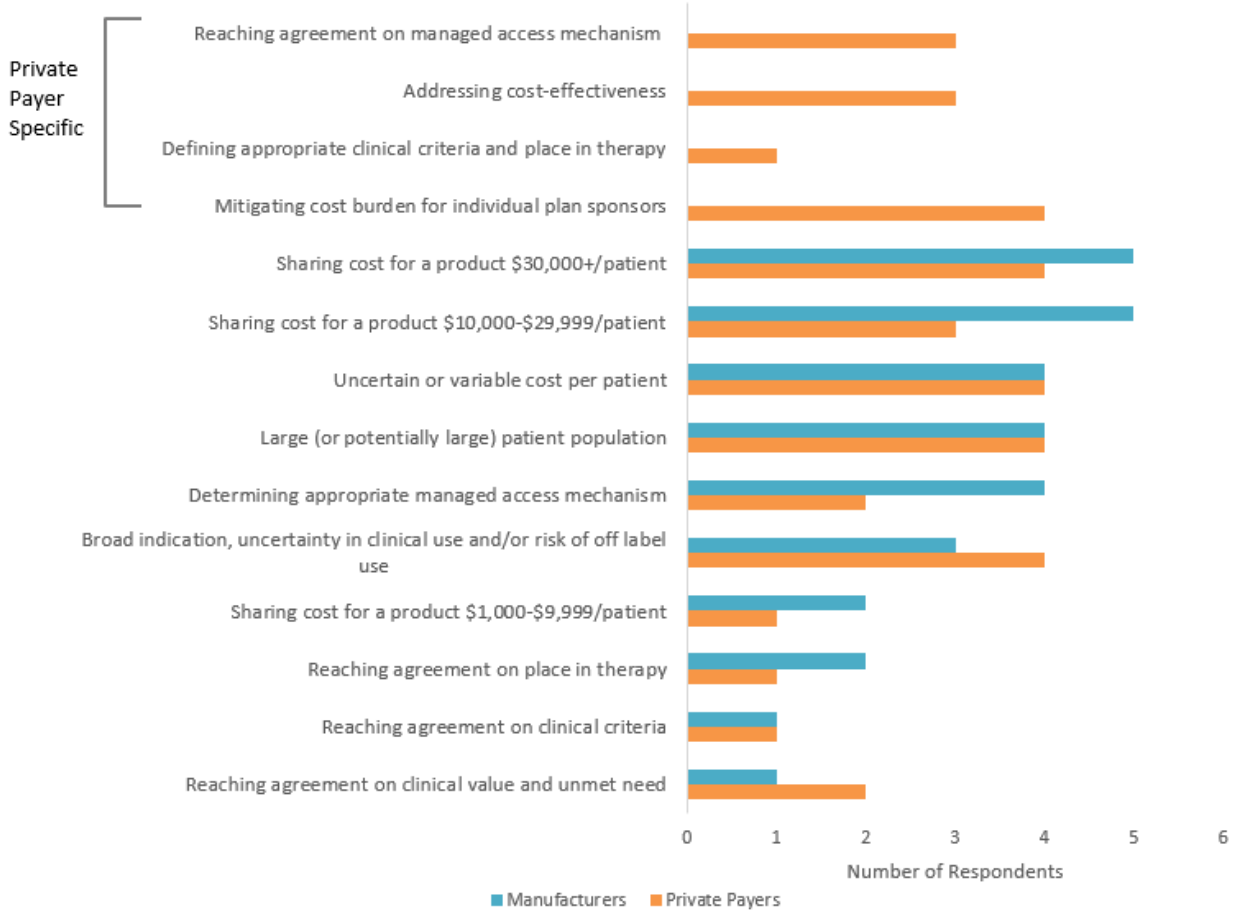
CENTRAL ISSUES ADDRESSED IN COMPLETED PLAS

There were 14 options in total available to identify the central issues negotiated in PLAs. Of those, nine were directly related to cost. Four options could be chosen only by payers. Figure 8 combines and compares the issues identified by manufacturers and payers. Respondents could select multiple options.

Twelve of 14 manufacturers responded to this question. There were 10 options available to this group and six were directly related to cost. The other four [(i) clinical criteria, (ii) place in therapy, (iii) broad indication, uncertain use and risk of off-label use and (iv) clinical value and unmet need] indirectly affect cost.

- Twenty-one of the 31 manufacturer responses identified cost-related issues that are addressed in PLAs.
- Five of 12 (42%) manufacturers identified sharing the costs for drugs priced between $10,000 and $29,999 and for drugs costing more than $30,000 as an important target.
- Four manufacturers chose uncertain or variable cost to patients, managing a large or potentially large patient population controlled by a payer, and managing a cost control mechanism as negotiation targets.

Figure 8. Main issues addressed from negotiating a PLA – Manufacturers and Payers



Of the six payers who responded, five issues were consistently selected by four payers. All are related to price, cost or budget impact. The five issues are:

- Mitigating cost burden for individual plan sponsors,
- Cost sharing for a product >$30,000 per patient,
- Uncertain or variable cost per patient,
- Large (or potentially large) patient population, *and*
- Broad indication, uncertainty of clinical use and/or off-label use.

Other issues can be categorized under clinical criteria and managing access. Of the 37 payer responses for this question, all but nine directly identified cost as the main issue addressed by PLAs.

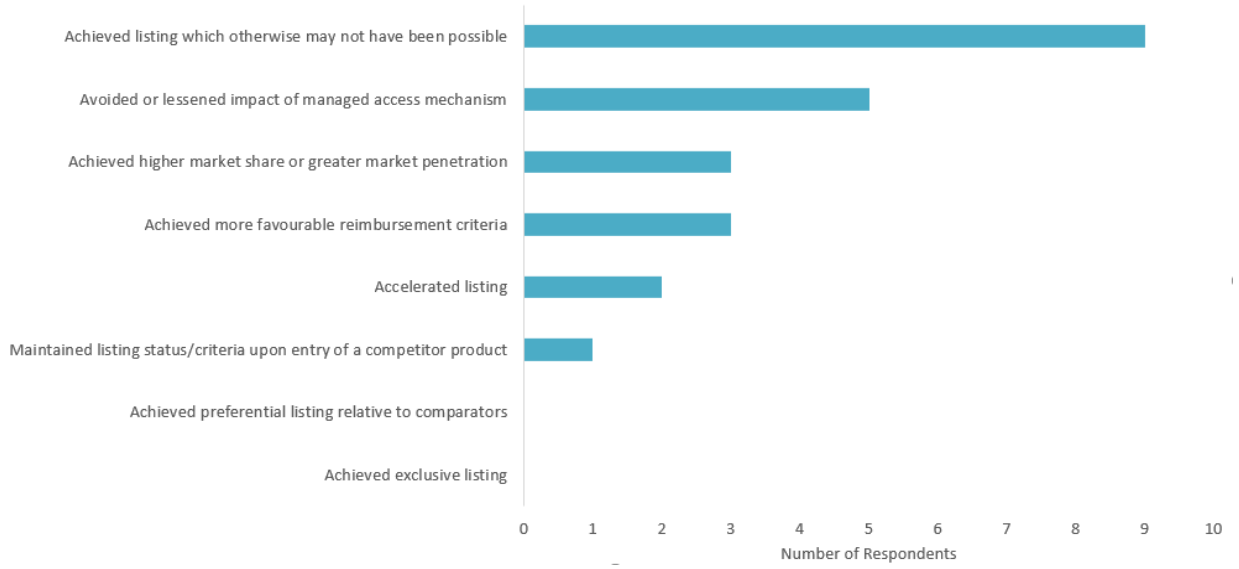
While cost is a high priority for both payers and manufacturers, the first priority for manufacturers is defining appropriate clinical criteria and place in therapy. Clinical criteria affect approval rates, regardless of cost, and therefore affects market uptake of a product.

PERCEIVED BENEFITS OF ENGAGING IN PLAS

Fourteen manufacturers responded to this question (Figure 9). The following were the highest perceived benefits of engaging in a PLA:

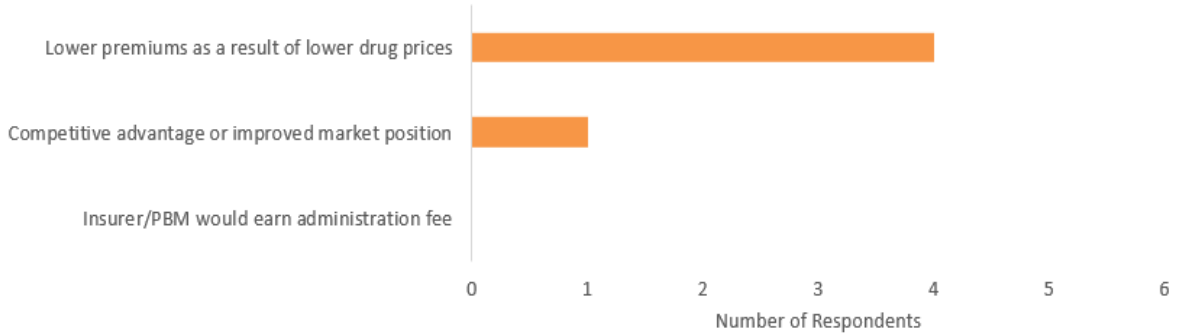
- Improved listing (n = 9; 64% of respondents)
- Avoided or lessened impact of managed access mechanisms (n = 5; 35%)
- Achieved more favourable reimbursement criteria (n = 3; 21%), *and*
- Higher market share or greater market penetration (n = 3; 21%)

Figure 9. Perceived benefits of PLAs – Manufacturers



Results were different for payers, as might be expected (Figure 10). Of the five payers who responded, four reported that lower premiums as a result of lower drug prices was the greatest benefit. One suggested PLAs provided a competitive advantage or improved their market position.

Figure 10. Perceived benefits of PLAs – Payers



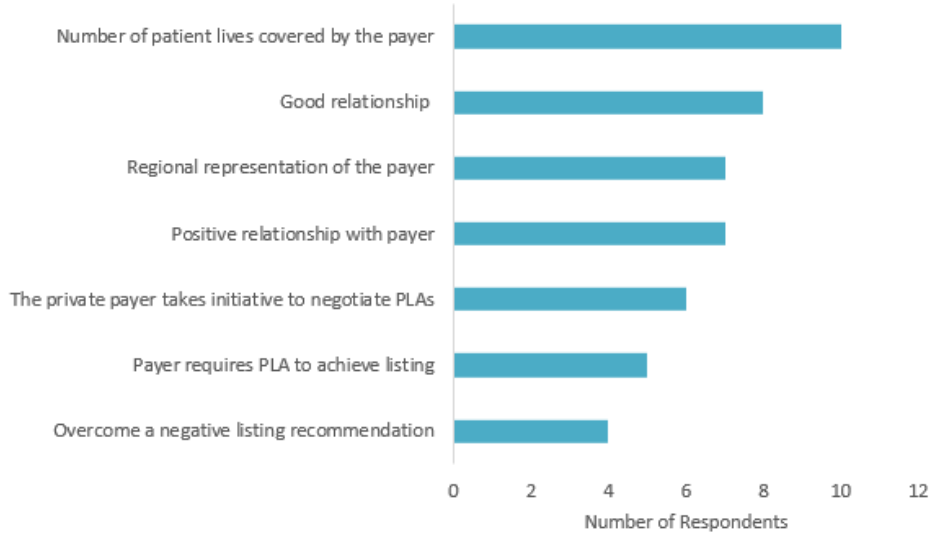
REASONS TO NEGOTIATE

At least half of the thirteen manufacturers who responded to this question reported the following reasons behind their interest in negotiating with specific private payers (Figure 11):

- Number of patient lives covered by the payer (n = 10),
- Good existing relationship with the payer (perceived to be easier to reach an agreement) (n = 8),
- Regional representation of the payer (n = 7), *and*
- A positive relationship (n = 7)

Clearly, not only payer size but also the relationship is very important. Taking the two similarly worded responses above, there were 15 responses that listed a good or positive relationship with payers as reasons to negotiate.

Figure 11. Reasons to negotiate PLAs – Manufacturers



All six payers reported that their reason for negotiating with manufacturers was to limit the risk of financial impacts from high price and/or high-volume drugs. Five indicated they wanted to limit risk exposure for clients and three responded that PLAs allowed them to provide coverage for a product not previously covered.

Figure 12. Reasons to negotiate PLAs – Payers

FACILITATORS AND BARRIERS FOR PLA NEGOTIATIONS

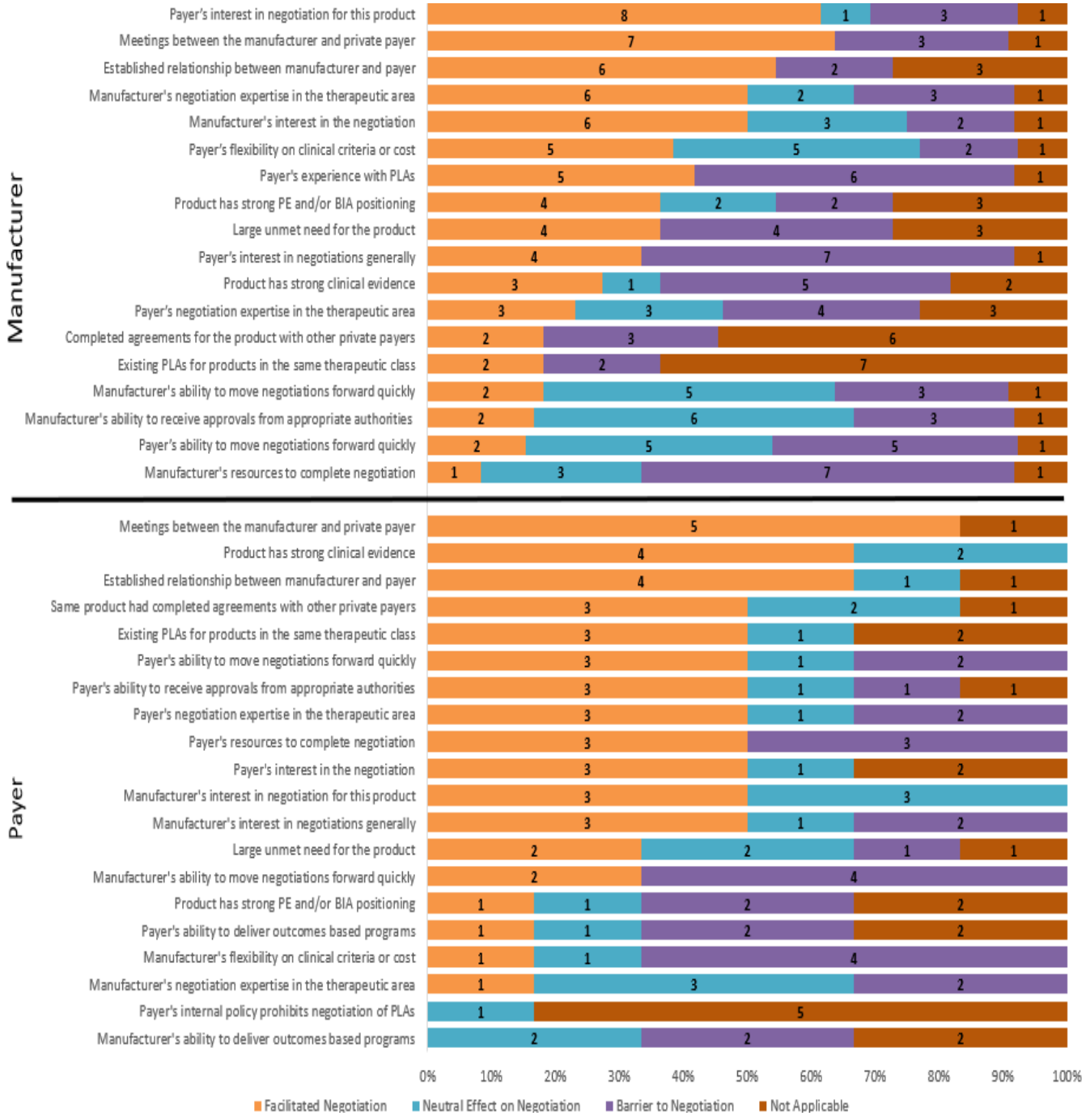
Figure 13 indicates that a barrier for six of thirteen manufacturers was their company's ability to receive approvals from appropriate authorities (e.g. global office, upper management). Other common barriers (each was selected by five manufacturers), were the payer's flexibility on cost and the payer's ability to quickly advance negotiations.

A main facilitator for eight manufacturers to negotiate a PLA was the payer's interest in negotiation for a specific product. Other facilitating factors include meetings between the manufacturer and private payer (n=7), the manufacturer's interest in the negotiation and their negotiation expertise in the therapeutic area (n=6), and having an established relationship between manufacturer and payer (n=6).

The main barriers for the six responding payers were the manufacturer's ability to move negotiations forward quickly and the manufacturer flexibility on clinical criteria or cost, each chosen by four payers. Three payers also noted inadequate internal resources to complete the negotiation.

For five payers, meetings with the manufacturer was the most important facilitator. Having an established relationship with the manufacturer and a product with strong clinical evidence both ranked second (n=4).

Figure 13. Facilitators and Barriers for PLA Negotiations – Manufacturers and Payers



NEGOTIATION INTERESTS

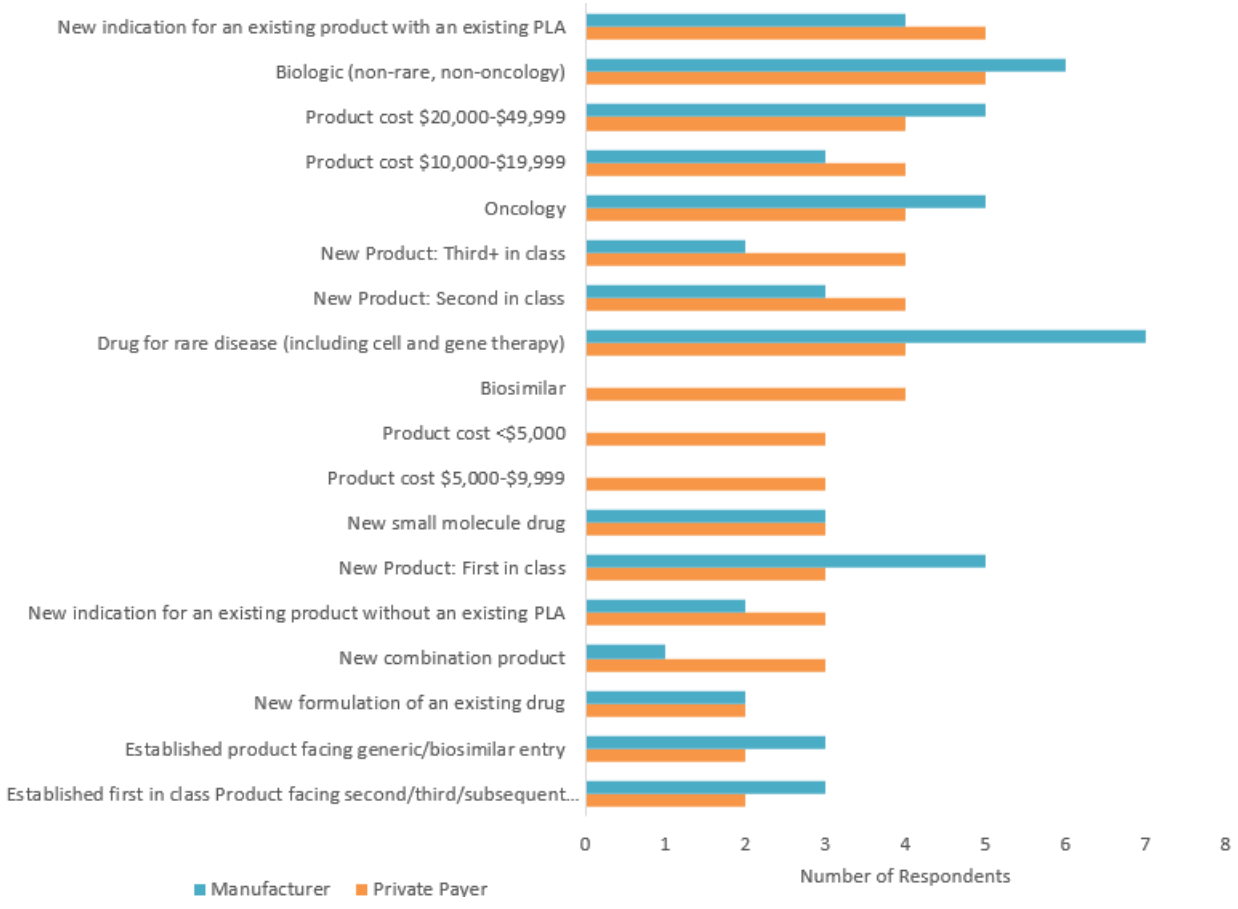
Manufacturers (n = 13) and payers (n = 6) expressed differences in the types of drugs they're most interested in negotiating (Figure 14).

Manufacturers wanted to negotiate PLAs for drugs for rare diseases (DRDs, including gene and cell therapies), as well as products costing more than $50,000, biologic drugs (non-rare, non-oncology), and new products that are first in class. Manufacturers are less interested in negotiating PLAs for lower cost products, and no manufacturer was interested in negotiating a PLA for a biosimilar.

Payers were most interested in PLAs for new indications and for non-oncology biologics. However, several other categories were marked by four payers, including (specialty) products costing more than $10,000, oncology products as well as biosimilars and new second- or third-in-class products where payers are likely to have stronger negotiation leverage and where there is client or advisor pressure to contain costs and risks. PLAs for drugs for rare diseases were also important for four payers.

When the interests of payers and manufacturers align, such as in new indications, biologics, oncolytics and drugs costing more than $20,000, it should be easier to reach an agreement. Manufacturers and payers should be particularly alert to where their negotiating interests are quite different, such as biosimilars, DRDs, drugs costing less than $10,000 and first- and third-in-class products.

Figure 14. Negotiation Interests – Manufacturers and Payers



CONFIDENTIALITY AND IMPLEMENTATION OF PLAS

Figure 15 presents confidentiality concerns and notes difficulty in implementing and administering PLAs. Seven of twelve manufacturers who responded (58%) reported difficulties in implementation or administration of PLAs after completing negotiations. In open-ended questions, manufacturers identified the following challenges:

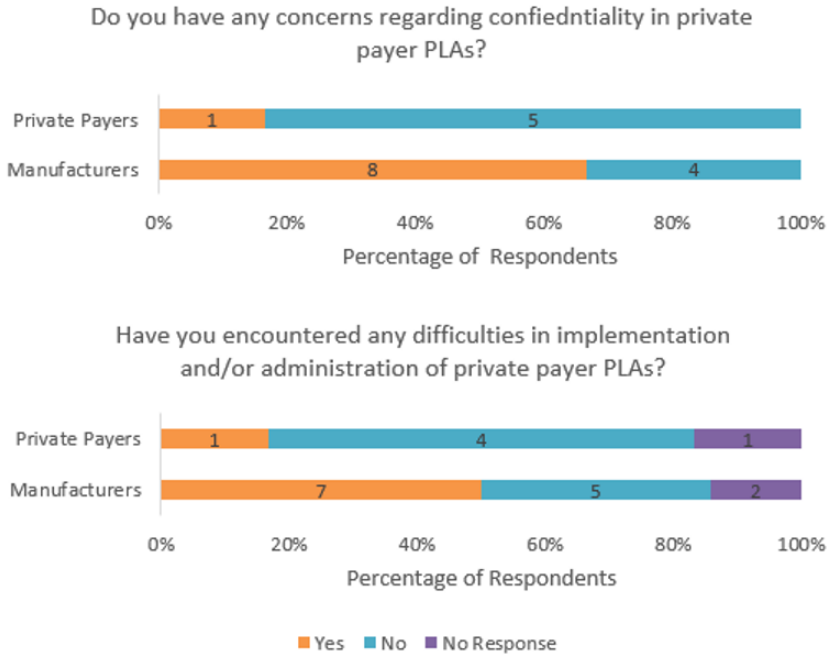
- *"Validation of claim details submitted by the payer"*
- *"Terms and conditions complexities on existing patients"*
- *"Reconciliation/tracking of eligible patients"*

Eight manufacturers (57%) also reported potential risks to confidentiality. They did not provide evidence or specific incidents where confidentiality had been threatened or breached, but in open-ended questions, manufacturers elaborated on their confidentiality concerns:

- *"Staff movement between industry, lack of understanding of each other's business models, of sales people talking about it, etc."*
- *"Rebate structure at POS (point of sale – i.e., at pharmacy when processing the claim) is definitely a weak spot."*

In contrast, five payer respondents reported that they had no concerns regarding confidentiality of PLAs. However, four payers noted they experienced difficulties when implementing or administering PLAs, which is similar to the response rate provided by the manufacturers.

Figure 15. Confidentiality and implementation of PLAs – Manufacturers and Payers



SUMMARY OF MANUFACTURER AND PAYER PERSPECTIVES: SIMILARITIES AND DIFFERENCES

As the negotiating parties to PLAs, manufacturers and payers have different objectives, motivations and customers. The manufacturer seeks to provide patients with access to their drugs and receive payment which recognizes the innovation and value the drug provides. Private payers endeavour to provide value to plan sponsors and improve patient affordability, as well as maintain or improve their competitive position. A confidential PLA can assist the two parties to come to mutually agreeable terms that serve their sometimes divergent purposes. This section compares the perspectives and experiences reported by the two groups.

These individual similarities and differences were already presented and their earlier references are indicated. They have been collected here to help illustrate points of convergence and difference across the PLA landscape.

Similarities

Manufacturers and payers are largely aligned concerning the types of drugs for which PLAs have been negotiated (Figure 4; new biologic drugs were the most frequent) and recent growth in the number of PLAs being negotiated (Figure 2).

Both parties indicated most agreements are not based on health outcomes and agreed that this is likely to continue. However, both expressed interest in negotiating health outcomes-based agreements in the future although there was a lack of certainty as to how such agreements might be structured, managed and delivered (Figure 6).

While some participants recognized their own internal processes could be a barrier to quick and effective negotiations, many also reported the other party being responsible for delays. Barriers include delays in achieving approvals, inflexibility on terms, limited resource capacity and understanding the other party's interest in the product or negotiation, particularly at a global level.

The parties were aligned on the main issues typically addressed by existing PLAs. Most frequently these included cost-effectiveness, sharing costs for products costing more than $30,000 per patient, managing uncertain or variable cost (either per patient or in total budget impact) and a large (or potentially large) patient population (Figure 8).

Half of manufacturer respondents (n = 7) and more than half of payer respondents (n = 4) reported difficulties in implementation or administration of PLAs (Figure 13). However, interviews suggest that these are usually resolved quickly.

All six payers and most manufacturers (ten indicated "yes" and four indicated "maybe") reported a continuing intent to negotiate PLAs in the next three years (not previously reported).

Differences

Not surprisingly, the motivations for entering PLAs differed between the two groups (Figure 11). All private payers reported the opportunity to achieve savings as a primary motivator. Half of manufacturers reported their primary reasons for negotiating private PLAs included: (i) to improve reimbursement potential for a high cost product, (ii) to access the large number of lives covered by the payer, and/or (iii) because the payer initiated the negotiation.

The main benefits of PLAs (Figure 9) reported by manufacturers were achieving a listing that otherwise may not have been possible and avoiding or reducing the impact of a managed access mechanism. For payers, the key benefit from PLAs is lower premiums as a result of lower drug prices, costs or budget impact (Figure 10).

Manufacturers and payers expressed differences in the types of drugs they're most interested in negotiating (Figure 13). In general, manufacturers were more interested in PLAs for high-cost therapies including drugs for rare diseases and specialty drugs, particularly if they cost more than $50,000 annually. Payers were most interested in PLAs for new indications and for non-oncology biologics. While no manufacturer wanted to negotiate a PLA for a biosimilar, several payers were interested.

PHASE 2 QUALITATIVE INTERVIEW RESULTS

In phase 2, five manufacturers and three payers participated in interviews. We present below a synopsis of the main themes that emerged from our analyses.

PAYER PERSPECTIVES

The research team conducted interviews between July 7 and August 7, 2020 with three different payers who had participated in the phase 1 quantitative survey. Four broad and connected themes were identified from the interviews:

1. Some payers have a structured, disciplined, and increasingly well-resourced and sophisticated approach to PLA negotiation.
2. Payers are motivated by competitive advantage with current and prospective group clients to further develop PLA structure and process.

> *"Plan sustainability has always been the key focus and, as well, patient health outcomes. So we want to be able to balance those two things. There's a need for access to innovative medicines and then there's a need for plans to be sustainable in the long term."*

3. Payers find drugs for rare diseases (DRDs) the most challenging drug category to manage and are looking for solutions to manage this risk more effectively.
4. With continued investment and motivation, payers are expecting greater value and demonstrable health outcomes from PLAs as one part of their market strategy.

NEGOTIATIONS

While our research indicates that not all payers have negotiated PLAs, the private market has nonetheless progressed significantly since 2015. Participants reported they have created a "templated" process to negotiating with drug manufacturers. This process includes investment in a variety of relevant clinical team members and health economic expertise, in-house for some.

> *"Global is very much aware and experienced in the expectations of negotiating with public payers and there's more of a priority given to them, but there is a need to educate global on private payer need …awareness that year-over-year the risk is growing in terms of the share of what private payers pay in the overall Canadian drug spend …so [there is] cost shifting more to private payers than in the past so they should take that into account in their pricing strategy."*

In both interviews and survey results, payers reported they were relatively satisfied with the negotiation process. Some comments were made about challenges to match negotiation cycles between the parties (i.e., timing, sense of urgency, or time spent with legal counsel). One payer stated that the importance of private insurance reimbursement should be reinforced to corporate and global drug manufacturer decision makers. Otherwise, if there are issues once terms are approved and signed off they are dealt with promptly.

A strong interest to negotiate PLAs in the future was expressed by payers both in the survey and in the interviews. The outcome of most PLAs is still a price discount or in some cases a defined limit on drug spending. One payer noted the elusive balance between cost control and access that enables better health. However, based

on participant comments, the necessary structure and expertise is not yet in place for outcomes-based agreements. One payer could see a need for health outcomes-based agreements for gene therapies coming to market in fall 2020. Another payer identified PCSK9 products as those appropriate for PLAs focused on health outcomes. Both identified a relatively short period for health outcomes evaluation of just six months. There will be concerns that health outcomes may be few and limited within six months, and that attribution to just the drug therapy will be difficult to prove at either the patient or population level.

COMPETITIVE ADVANTAGE

Survey and interview results support that PLAs provide a competitive advantage in marketing discussions and finalist presentations during which a carrier solicits an employer's business. One payer told us that "*We present every time on our PLA approach*." To support their claim, participants stated their companies include aggregated PLA savings in marketing and communications and release the names of the products for which they have PLAs in place.

PBMs either have or are moving to point-of-sale (PoS) systems to distribute savings immediately, rather than via rebates after the fact. In these systems, PLA discounts are adjudicated through the PBM network at the pharmacy counter and therefore the plan sponsor and plan member immediately realize their savings. One payer reported that roughly 75% of PLA products are reimbursed through a PoS system: *"[We] really drove the development of the capabilities with our PBM when it comes to PLAs… o*ur *standard approach is that the PLA will be administered at point of sale and will serve as a move to reduce the eligible cost for the plan member and plan sponsor.*" This is a competitive advantage to plans that do not use a PoS system. In this case the payer, typically a smaller PBM, must calculate savings after the drug is dispensed and if possible, rebate the PLA savings to plan sponsors. The payer will then report savings to Administrative Services Only (ASO) clients through reduced premiums or quarterly reporting, and to fully insured groups through lower rates. Absent a PoS system, the member is left to pay "retail." Given the still-limited transparency of negotiations, plan sponsors must trust their insurers to pass on their full share of savings.

On behalf of their clients, one payer noted they leverage PLAs as "*just one of many tools*" to maintain their competitive advantage in lower drug plan costs and to ensure plans continue to be sustainable. That same payer stated: "*We are continuing to invest in [our] ability to negotiate better discounts, deeper discounts, and more competitive price reductions than some of the other carriers*…." The survey results indicated that payers target PLAs at high-cost drugs, typically those costing more than $10,000 annually, as well as lower priced drugs with significant budget impact. One payer reported they are continuing to expand the use of PLAs "*…and expand beyond just your typical high-cost drugs because we see a need and opportunity to lower costs even on medium to lower-cost drugs as well in the future*."

Survey and interview results indicate that productivity-related data rarely accompany a new drug submission. Two payers noted that manufacturers had recently presented new value-based approaches. One payer reported these are "*…happening already… a few [pharmaceutical] companies have come forward with what they would call 'disruptive business models'…so we're working with a couple of them right now. I'm hoping that we'll be in play before the end of 2020*."

DRUGS FOR RARE DISEASES

Payers agree that DRDs are the most challenging reimbursement category. "*It's the toughest category to deal with, there's no question. You know some of these drugs are 500, 600 thousand dollars so a 20 percent discount on that is really not going to make a lot of difference in terms of its impact.*" All participants noted they are looking for more comprehensive solutions to manage this risk more effectively, which includes:

- Evaluating cost effectiveness,
- Managing risk through funding arrangements or pooling thresholds,
- Unilateral contract changes by an insurer,
- Capping the number of patients reimbursed

One carrier stated that they exclude DRDs under managed formularies. In Canada, regional carriers often have a much higher proportion of managed plans than the national insurers.

DRD reimbursement is complicated by different coverage among public plans, making it challenging to manage on a national basis. The CLHIA favours federal funding for DRDs.[14] One participant reported a new insurance industry DRD pooling alternative is currently under discussion with CLHIA and its member companies.

"We're funding a lot of rare drugs, but the super expensive drugs for rare diseases, a number of those we're not covering at all on managed plans because they're above affordability thresholds."

FUTURE PRIORITIES FOR PRIVATE PLAS

Payers are interested to develop the PLA landscape and negotiate more sophisticated agreements, moving beyond PLAs centered solely on price and cost. Opportunities exist for manufacturers that are willing to work with payers to create "*more holistic partnership agreements*" with more demonstrable value. This includes a somewhat simpler and more immediate improvement through value-based agreements. Health outcomes-based agreements are also attractive if they include value-based services, such as home delivery, virtual coaching, mobile apps and data.

The largest payers already have superior systems that may differentiate them successfully if they can track and report these higher-order outcomes. PBMs can use their scale to help smaller payers effectively pool their drug business and provide additional expertise or economy of scale at roughly the same level as their much larger industry competitors. Despite increasing scale and sophistication in the private market, the pCPA still offers manufacturers a more predictable, consistent, efficient, and unified approach to drug pricing and listing negotiations, which may even justify more generous concessions.

"[Manufacturers] are not even bringing it up to say, 'do you require a PLA?' So, they're assuming we do not need a PLA. That's their standard position."

As previously noted, two payers stated that their PLAs are not seen to be as important as agreements with the pCPA by global drug manufacturer headquarters. This occurs despite evidence that many new drugs are available under private insurance plans months before provincial governments list them. (This may not apply to high-cost drugs that require a PLA from both payer groups.)

MANUFACTURER PERSPECTIVES

The research team hosted interviews July 6-24, 2020 with five different manufacturers who had participated in the phase 1 quantitative survey. Four key themes were identified:

1. Private PLAs have generated opportunities to expand patient access and are now perceived to be a part of the cost of business, at least for some types of drugs.
2. Manufacturers noted that their own company's senior and global leadership are not always convinced of the need to negotiate in the Canadian private market.
3. The negotiation process, though generally a positive and amicable experience, can impede the goal of achieving timely access.

> *Positive would be if [payers] just accepted [manufacturers] have done their due diligence and the price is right and "let's list it". But the good side of [PLAs] are in cases where a payer or insurer is struggling to justify what they think is a high price, they're getting more sophisticated at understanding whether it really is a high price… It creates opportunities where doors might be closed."*

4. Compared to the pCPA, manufacturers noted the private process to be more nimble although more labour intensive due to the number of carriers with which they must negotiate.

CHANGES TO PLA LANDSCAPE SINCE 2015

Regarding changes to the landscape since 2015, the manufacturers reported increases in capacity and sophistication to both negotiate and implement agreements. For payers, they noted the establishment of programs such as DrugWatch, SMART and Drug Risk Management as evidence of payers' growing focus on PLAs. They suggested payers' technological capacity to offer real-time, point-of-sale discounts immediately shared with patients and plan sponsors had "opened the door" for increased activity since 2015. Several manufacturers noted new positions or roles had been created within their organizations focused on supporting and implementing private market access strategy, including PLAs, since 2015.

> *"Not all manufacturers have been on board with regards to [private] PLAs, and the direction from the top down has been: "We're not engaging in PLAs; we're not giving away rebates." I definitely think, in the past five years it's been an eye-opener for a lot of the leadership teams, and they realize they really have to engage in PLAs in order to maintain or generate listings… I definitely see there's more of an appetite and more of a realization that this is the way of the world if we want listing and access for our patients."*

Manufacturers reported that both payers' and manufacturers' perspectives on PLAs have evolved. Compared to five years ago, manufacturers now generally acknowledge, at least for certain types of higher cost or budget impact drugs, that PLAs are "*the cost of doing business now*." However, another manufacturer noted "*sometimes a negotiation in the private space is just not appropriate depending on the drug*."

Manufacturers reported an increasing awareness about what other payers are negotiating and an aggressive stance among some payers to ensure they remain competitive by offering lower costs through PLAs.

Manufacturers reported these changes have been both positive and negative: Positive because they have created opportunities in some cases where patient access would have otherwise not been possible or would have been limited; and negative since PLAs require financial concessions to be accounted for in a product's gross-to-net and other costs such as investing in negotiation planning, agreement monitoring and administration which they did not have only a few years ago.

"I found the dialogue was meaningful and there was no reason for me to think that anybody was playing games. Everybody looked at numbers and clinical [information] in a very mature, thoughtful, caring way. It gave me faith process can work the way it's supposed to work."

NEGOTIATION BARRIERS AND FACILITATORS

"Canada being 2% of the global market is a huge challenge… because we need to answer to global. I have my hands tied where I want to be able to offer an insurer a bigger rebate but I don't have global approval and there's a long process to get approval"

Manufacturers reported the biggest challenge in the PLA process can sometimes be internal to their own company. Senior leadership, especially in large, globally-based pharmaceutical companies, may need to be convinced of the need to negotiate in the Canadian private market.

For this reason, one manufacturer noted that laying the groundwork with their senior leadership or global team could facilitate a quicker, more effective process once negotiations are underway.

Negotiations are easier when manufacturer and payer goals are aligned: "*We're all out for same cause. We all want access for plan members and patients for the best possible health outcomes. [Insurers] also have their leadership and customers to answer to and the employers, who are spending, their costs are going up too*."

MOTIVATIONS AND LEVERAGE

Manufacturers reported that for some products or market circumstances (such as drugs for rare diseases, or biologics especially where biosimilars are marketed) PLAs are practically mandatory to achieve listing with some payers. As one manufacturer reported: "[Payers] hold the keys to the castle in terms of actual access".

Some manufacturers indicated large payers generally have more leverage, but not all manufacturers agreed. Where PLAs are not mandatory, manufacturers could offer PLA terms to assist in access. They could, for example, propose comparable criteria with competing products, or terms that mitigate the effect of prior authorization or other mechanisms that the payer would otherwise use to control cost.

Manufacturers saw their leverage resting largely on their product's strong clinical evidence and ability to fulfill high unmet need, with the latter being reported as "*a compelling reason for payers to move quickly*." Manufacturers also noted that apart from the two negotiating parties, patient groups have also been effective at exerting influence within the private PLA process.

SATISFACTION WITH PLA EXPERIENCES

Manufacturers reported they were generally satisfied with both their negotiation experiences and the results of agreements negotiated to date. They described discussions with payers as "*amicable*" and generally focused on optimizing access for patients.

Despite general satisfaction, manufacturers expressed one drawback: the negotiation process can delay access. They noted the process of taking information up the payer hierarchy can delay progress, as can the post-negotiation legal contracting phase. However, most participants reported shared accountability for such delays. Nonetheless, manufacturers indicated they'd like to work with payers to improve this aspect of the PLA process.

COMPARED WITH THE PUBLIC PAYER PLA EXPERIENCE

Manufacturers reported some similarities between private and pCPA PLAs, but indicated some key differences both in the process and outcomes.

The private PLA process is often less formal and structured and so payers can be more "nimble" than pCPA to make decisions more quickly. Even though each of the three largest insurers cover more lives than any provincial drug program except ON and QC, the pCPA tends to have more negotiating leverage than any single carrier. They reported private negotiations can be more labour-intensive than pCPA given the need to engage with each payer individually, and to learn each payer's unique approach.

Manufacturers also recognized the important differences in the mandates, objectives, expectations and infrastructure of public versus private payers, resulting in different discussion priorities, levels of flexibility and – ultimately – agreement outcomes. Because pCPA adheres strongly to recommendations from health technology assessments, manufacturers reported that private payers can often be more flexible in their agreement parameters.

Comparing the challenges of negotiating pCPA versus private PLAs, one manufacturer indicated that achieving internal approval for private PLAs is more difficult since senior leadership tends to better appreciate the role of public listing agreements. They may not believe private payers should receive any price concession, let alone a substantial one.

> *"Because the public side owns the healthcare system too, it's easier to make the case that there are savings elsewhere in the system. I think it is a little more challenging on the private side because the benefits [the payer is] supposed to accrue are lost if the employee moves to another company, and there are blended plans, et cetera."*

THE FUTURE OF PLAS

Manufacturers expect private PLA activity to increase over the coming years, both with more payers getting involved, and more drugs requiring PLAs to secure listing as payer capacity grows. As one manufacturer said "*More payers that aren't capable now, they are certainly well aware of what exists on their side of the industry and there are more and better solutions that are being explored and they are going to want to get on that same boat*."

Manufacturers also agreed private PLAs would continue, despite uncertainties in the market access landscape. According to one manufacturer: "*The PLA train is on the track and rolling and it's a tough train to stop*." They noted effects of PMPRB reform will – and indeed already have – affected private PLA negotiations: "PMPRB reform will create considerable uncertainties for manufacturers within both the public and private market." However, other policy developments such as a national drugs for rare diseases strategy or national pharmacare were considered too

far in the future to affect private PLA discussions today. However, those developments may change the nature of private PLAs in the future.

DISCUSSION

THE EVOLUTION OF PLAS: 2015 TO 2020

In 2015 we reported that most of the private payer PLA activity had occurred in the year just past. We wondered whether the private market would simply follow the pCPA pattern, or whether different dynamics and interests were at play.

There have been some significant changes since 2015:

1. Today, PLAs are more often considered a condition of listing, certainly for managed formularies and for certain types of drugs.

2. While payers were only beginning to structure and administer PLAs in 2015, the larger payers now have substantial teams in place. In 2020, a negotiator typically leads a small team consisting of clinical (often a formulary review team), actuarial, claims, legal and regulatory representatives. A staff or consulting economist may be involved, and at least two payers have highly qualified health economists on staff.

3. Most PLAs remain focused on financial outcomes such as price reductions, drug budget impacts, or sometimes an overall cap on spending for a particular drug or therapeutic class. Perhaps due to potential inconsistencies in definitions, we are not aware of any PLAs that track and report health outcomes or incorporate “indirect” health spending from absence, disability or presenteeism.

4. In 2015, some payers reported they expected to negotiate more PLAs in the coming years. Results from our 2020 survey indicate there are many more PLAs now.

5. More point-of-sale (PoS) technology is implemented at the pharmacy by payers, particularly the largest payers through their PBM. This allows plan sponsors and patients with coinsurance to directly participate in the benefit of a lower negotiated price. Older technology focuses on preventing pharmacists from knowing the amount of PLA discount.[6]

6. Our interviews indicate payers are now reporting which drugs have PLAs and their aggregate savings to their clients and the market at large. While this is similar to pCPA website reporting, private PLAs have become a competitive advantage. For example, Sun Life recently communicated that its PLAs had saved plan sponsors and members more than $100 million in the previous five years. Further, they expect “hundreds of millions of dollars in savings for plan sponsors over the next five years.”[15]

[6] Large PBMs such as Telus Health and Express Scripts Canada use point-of-sale (PoS) technology to provide discounts directly to patients when they are eligible for a PLA, but not all their plans operate this way. Other PBMs and insurers have limited PoS technology.

Insurers believe PLAs are a source of competitive advantage even though the savings cannot be revealed to their clients or the broader market.

Some aspects are essentially unchanged compared to 2015:

1. Individual carriers continue to consider their own PLA negotiations. There is not yet an industry-level standard, nor is there any indication that the CLHIA will become part of the pCPA process or that centralized negotiations by insurers and PBMs are under consideration.[7] The Competition Act presents some possible constraints to industry-level behaviour but the boundaries have not been tested to our knowledge.

2. The net benefits of PLAs are still difficult to identify. Manufacturers may achieve access for new products, but typically must provide price reductions through rebates or PoS technology. Insurers and PBMs get lower prices and their paid claims levels are somewhat lower, but they incur extra cost for agreements they cannot fully disclose to their clients. While there is no direct evidence, it is believed that private PLAs generally do not achieve the same level of discounts as pCPA agreements.

3. There is no indication that private PLAs have become more transparent, which was expected in 2015. The emphasis on confidential terms is similar to pCPA negotiations and is consistent with worldwide practices. Similar to 2015 results, the 2020 survey found that manufacturers are not fully confident that contract terms and conditions are sufficiently restricted to ensure confidentiality within insurer or PBM operations, although there are no known examples of a breach by any payer.

4. Data are sometimes collected by manufacturers to describe the potential effects of new drugs on absence, disability, presenteeism, or other productivity metrics. However, it seems these data are, for the most part, not currently being tracked for purposes of PLAs. Notionally, these costs are very important to plan sponsors although employers still do not always completely or accurately compile these data in their own operations. Such metrics could add significant value and scope to a PLA negotiation and assist plan sponsors in moving their own organizational scorecards forward.

The 2020 survey and interviews indicate private PLAs have become standard practice for many new drugs, particularly those with high cost per patient or budget impact, or uncertainty in potential use. For now, most PLAs continue to focus on drug price reduction. Drug manufacturers believed PLAs could assure or speed market access though this latter assumption is increasingly questioned. Unlike pCPA, it is not clear how many private PLAs exist, or what aggregate savings have been achieved. Further, PLA opacity means it is unclear how or whether all negotiated discounts are passed through to plan sponsors and members, but increased use of PoS technology is making it easier to address this concern.

[7] In recent years, the pCPA negotiated a market-wide agreement for generic pricing (2018-2023). pCPA mandated transparent discounted pricing for biosimilars in 2016 and updated its policy in 2018. See: https://www.pcpacanada.ca/. There is no indication that private payers or the CLHIA actively participated in these initiatives.

SUMMARY AND RECOMMENDATIONS: THE PRIVATE PLA LANDSCAPE IN 2020 AND BEYOND

Five specific developments encourage growth in private market PLAs.

1. The pCPA has reportedly negotiated over two billion dollars in price discounts since 2010. That figure is compelling for private payers that have a fiduciary interest in putting the interests of their clients first and that wish to create or maintain a competitive position. If provinces can get such large discounts, then carriers will seek similar accommodation to lower their clients' drug plan costs.

2. The increasing cost and share of biologic drugs have encouraged all payers to support biosimilar market access. With a number of public and private plans moving or considering a biosimilar-first or switching policies, private payers remain in a strong bargaining position to negotiate PLAs for biologics. As long as they offer payers competitive pricing via PLAs, the original manufacturer may be able to retain much of their biologic market share.

3. Private payers have expressed concerns about 'indication creep' for high-cost drugs already reimbursed and for other drugs that may put significant pressure on plan budgets. Increasing budget impact makes new indications and expanded prescribing a prime target for PLAs.

4. The transition from traditional, infused cancer therapies administered in hospital to orally-administered oncology drugs and immunotherapy oncology products dispensed in private clinics has put pressure on private plans and created payer resistance in a category traditionally covered by governments. Oncology products are already frequent targets for PLAs and this trend is likely to continue given the robust cancer drug pipeline. Public coverage gaps for these newer products in some provinces support this momentum.

5. Finally, both manufacturers and private payers seem hopeful that a national publicly-funded solution will be developed to ensure access to effective drugs for rare diseases. A national strategy was announced in the federal government's 2019 budget. However its future and timelines remain undefined. Until then, private payers will either insist on PLAs for these special drugs, severely limit reimbursement, or they will simply refuse to list them.

Based on both survey data and interviews, there are opportunities to improve the private PLA landscape.

1. Manufacturers reported concerns with confidentiality, particularly the back-calculation of rebates using PoS purchasing software. However, both payers and manufacturers reported positive experiences with the other party in their efforts to address any issues related to confidentiality or administration. This concern may be more notional or theoretical than actual, but consequences could be impactful if confidential PLA details were revealed.

2. Ensuring that maximum savings are available to plan sponsors is an important value proposition for payers. The extent to which lower premiums are realized by each plan sponsor will largely depend on the funding arrangements in place and how carriers administer PLA-based savings. Self-insured groups with ASO contracts will receive a direct benefit when private payers pass on all savings directly to the plan sponsor. Small, fully-insured groups may achieve savings indirectly, on an aggregate basis through lower claims administration expenses or lower trend factors. Interviews revealed that insurers are already using PLAs as a marketing tool to retain business and attract new clients. This suggests we can expect more PLAs for drugs

with high market impact and even more emphasis on employer savings. Pressure is likely to continue for greater transparency by manufacturers.

3. Manufacturers that are interested in PLA negotiations should have a very clear understanding that while strong, trusted relationships are highly valued, payers reported their overriding priority is to limit risk by reducing prices, costs and budget impact.

4. Private payers should be aware that both their relationship with manufacturers and the size of their block of business and regional representation play a key role in determining their negotiating leverage. This suggests the four or five largest carriers may continue negotiating their own PLA contracts. For smaller insurers to remain competitive, PBMs may play a larger role in providing the scale and leverage needed to realize PLA savings comparable to large insurers.

5. At an industry level, there has been some interest in leveraging the collective power of all private insurers and PBMs to either negotiate collectively with manufacturers or to merge their negotiations with pCPA. However, it is not certain that a single negotiation will be in the best interest of the diverse population, financial and policy interests served by each payer group. The pCPA would also have to be willing to share control and likely accept less favourable terms. Another barrier to consolidated negotiations is that insurers could no longer position their PLAs as a competitive advantage.

6. At least one opportunity would allow private payers and manufacturers to reinforce the generally positive working relationship that has arisen through years of PLA negotiations. Both parties are interested in creating PLAs based on health outcomes. Manufacturers could add value by supporting payers with additional resources. Manufacturers and payers could mutually develop industry-level and even national standards that cover the process and structure of this emerging form of PLA.

Since 2015, the private PLAs landscape has developed considerably. PLAs are a valued and growing tool for private payers to gain competitive advantage and manage risks, prices, costs and budget impact. Manufacturers increasingly recognize private PLAs to maintain or gain competitive advantage in existing markets and to secure initial access in new markets. PLAs will continue to grow and allow both parties net advantages they would not otherwise achieve.

STUDY LIMITATIONS

- This study included a purposive selection of participants who voluntarily chose to complete a survey and/or an interview. They were known contacts of the research team and qualified by them as appropriate respondents for the study. This sample may not be representative of all their industry peers.
- There is likely recall bias and recency effects present in survey respondent reporting of the number and types of PLAs negotiated.
- The COVID-19 pandemic may have constrained our ability to recruit a larger, more representative sample from each industry group. Some potential participants who were invited to participate in the survey declined due to resource limitations linked directly or indirectly to the pandemic.
- Although private PLA experience was not a condition to participate, some invitees declined to participate because they had no experience. Therefore, our results may not accurately indicate how many Canadian manufacturers or payers are active in the private PLA landscape. We believe our results reflect the experiences and perspectives of those stakeholders with private PLA experience.

ABOUT THE AUTHORS

Courtney Abunassar is Associate Director, Market Access and Policy Research at PDCI Market Access. As a member of PDCI's Reimbursement Strategy Team, Courtney contributes to the development and implementation of public and private market access strategies that successfully optimize pricing and reimbursement. Her role includes performing strategic market access assessments, leading payer research and policy analysis projects, leading reimbursement submissions and contributing to the development of their core components, as well as supporting preparation of expert reports for patent litigation cases. In addition, Courtney conducts research and writes policy reports concerning a broad range of health and pharmaceutical policy topics in Canada.

Prior to joining PDCI in 2011, Courtney worked in strategic policy analysis and communications positions with the federal government and not-for-profit health organizations. Contact: courtney.abunassar@pdci.ca

Denise Balch is Principal Consultant and President of Connex Health Consulting. Since founding Connex Health in 2000, Denise has worked with her clients, including plan sponsors, not for profits, and the pharmaceutical industry, to develop unique solutions to complex problems in employee and workplace health, group benefits design and reimbursement.

In 2013 Denise was recognized by the Rogers Workplace Health and Benefits Awards – 2013 as Lifetime Achievement Finalist for this work. She is a frequent contributor to industry publications and chairs several group benefits and private healthcare educational series. Denise also serves as a voluntary Board member of the Temiskaming Hospital and as chair of the Quality Committee. Contact: denisebalch@connexhc.com.

Chris Bonnett is Principal Consultant, H3 Consulting. He provides practical prescription drug policy research for private and public drug plan leaders and advises on strategies to improve health in the workplace. His communication credits include dozens of health-focused articles and invitations to speak at more than 125 conferences and webcasts across Canada and in the US.

Chris has been a volunteer director on the Boards of four health service organizations including a 2019 appointment to the College of Dental Hygienists of Ontario. He teaches the business case for workplace health to third-year degree students at Humber College. He has been a member of the Sanofi Canada Healthcare Survey Advisory Board since 2003. He holds a Master's degree in Health Science from the University of Toronto, and a PhD from the University of Waterloo. His dissertation examined how to achieve universal drug insurance. Contact: chris@hthree.ca

Mark Fleming is an independent pharma health care consultant acting as a Strategic Advisor supporting PDCI's pricing, market access and policy research initiatives. A pharmacist by training, Mark has had close to forty years of experience; initially as the Pharmacy Director at a northern Manitoba health centre then followed over thirty years in the pharmaceutical industry. In industry, Mark's leadership experience spans government affairs, health policy, strategic pricing, marketing and sales, first with Eli Lilly Canada, and more recently at Janssen Inc. (Pharmaceutical Companies of Johnson & Johnson). Mark has also served in leadership roles on several industry association committees with Innovative Medicines Canada and BIOTECanada. Contact: mark.fleming@pdci.ca

Julia Shen is Associate, Health Economics and Policy Research at PDCI Market Access. Julia is part of the Health Economics team and her role focuses directly on supporting PDCI's expertise in developing pharmacoeconomic submission components. Julia also provides strategic assistance on market access assessments, policy research, data analytics, and external engagement with clients. At PDCI, Julia is actively involved in the Policy team and has both supported and developed work in pricing policy, assessment of access barriers for medications, and national pharmacare.

Julia has completed a Masters of Science in Sustainability Management (MScSM) at the University of Toronto and has a Bachelor of Science (Specialization in Biochemistry) from Queen's University. Contact: julia.shen@pdci.ca

GLOSSARY OF TERMS

Administrative Services Only (ASO): This is a funding approach that transfers all contractual liability for claims payment to the employer or other plan sponsor, typically for extended health and dental benefits. An insurance company or third-party administrator is retained only to provide claim handling and other administrative services such as tax remittal, as well as stop loss pooling to protect a plan sponsor against high claims levels.

Drugs for rare diseases (DRDs): While there is no standard Canadian definition, "rare" means affecting no more than one person in 2,000. There are about 7,000 rare diseases that together affect about 8% of Canadians.[16] At December 2018, 79 DRDs had been approved with annual sales of $1.8 billion.[17]

Non outcomes-based programs (patient level): Price is discounted for each patient.

Non outcomes-based programs (population level): Discounted price is based on total eligible patient population.

Outcomes-based program with performance-linked reimbursement: Discounted price is based on quantitative evaluation of patient outcomes within defined metrics.

Outcomes-based programs with conditional coverage: Discounted price is conditional on meeting defined patient outcomes.

Pan-Canadian Pharmaceutical Alliance (pCPA): pCPA is one part of the Canadian drug approval and reimbursement process. The pCPA negotiation begins for the majority of new drugs after a recommendation is published by CADTH and/or INESSS. pCPA uses these recommendations and other factors to determine whether it will negotiate a PLA with the manufacturer. pCPA members include public drug plans from all provinces and territories, as well as Non-Insured Health Benefits, Correctional Services of Canada and Veterans Affairs Canada.

Point of Sale (PoS): The time and place where a retail transaction is completed. Pharmacy POS systems help pharmacies and pharmacists electronically accept payments, track available inventory, manage customers, and confirm or approve purchase orders. These solutions are implemented by retail, clinical, and independent pharmacies alike.

Private Payer: This term includes employers that ultimately fund private drug insurance, as well as insurers, pharmacy benefit manager (PBMs) and sometimes third-party administrators.

Product Listing Agreements (PLAs): Confidential agreements negotiated between a drug manufacturer and a public or private payer or its representative (e.g., pan-Canadian Pharmaceutical Alliance) regarding the specific terms under which the payer agrees to reimburse (cover) a drug.

REFERENCES

1. Sutherland GD, T Dinh, 2017. *Understanding the Gap. A Pan-Canadian Analysis of Prescription Drug Insurance Coverage*. The Conference Board of Canada.
2. Canadian Institute for Health Information, 2019. *National Health Expenditure Trends, 1975 to 2019*. Data Tables - Series G.
3. TELUS Health, 2020. *Data Trends and National Benchmarks Report, Retrospective 2019*.
4. Express Scripts Canada, 2020. *2020 Prescription Drug Trend Report*.
5. Morgan SG, MK Friesen, PA Thomson, JR Daw, 2013. Use of Product Listing Agreements by Canadian Provincial Drug Benefit Plans. *Health Policy* 8(4): 45-55.
6. pan-Canadian Pharmaceutical Alliance, 2020. pCPA Activity Overview. [viewed 5 Aug 2020].
7. Sun Life Financial, 2019. *Bending the Benefits Cost Curve*. https://www.sunlife.ca/static/slf/Mattest/Site%20Administration/Images/Pharma%20Booklet%20Bending%20the%20Cost%20Curve%20E.pdf.
8. Manulife, 2015. *Introducing Manulife DrugWatch*.
9. PDCI Market Access and H3 Consulting, 2015. *Report 1: Negotiation-Naïve & No Interest in Negotiating a Private Payer PLA*.
10. PDCI Market Access and H3 Consulting, 2015. *Report 2: Negotiation-Naïve & Interested in Negotiating a Private Payer PLA*.
11. PDCI Market Access and H3 Consulting, 2015. *Report 3: Experience Negotiating Private Payer PLAs*.
12. PDCI Market Access and H3 Consulting, 2015. *Report 4: PLA Perspectives, Comparison and Contrast*.
13. Carlson J, S Sullivan, L Garrison, P Neumann, D Veenstaa, 2010. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. *Health Policy* 96(3): 179-190.
14. CLHIA, 2019. Budget measures offer sensible steps to achieve pharmacare for all who need it. News Release, March 19.
15. Op cit. Sun Life Financial.
16. CADTH. Drugs for rare diseases: a review of national and international health technology assessment agencies and public payers' decision-making processes.
17. Lungu E, 2019. *What is the "Expense" for Expensive Drugs for Rare Diseases?* PMPRB. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1461&lang=en.