ACTUARIAL ANALYSIS OF THE BIOLOGICS SAVINGS PARTNERSHIP™

Executive summary

June 2020

BACKGROUND

The proportion of Canadians with access to coverage through private insurance has increased from 71 to 79 percent in the last decade.[1] Compared to 1990, private insurance plans in 2018 had spent about 8 times more for prescription drug coverage.[2] The rise in drug spending is being driven in part by the increasing utilization of biologics, as well as biosimilar biologic drugs (also known as "biosimilars").*[3,4] Currently, spending on specialty drugs, including biologics, represents 29 percent of the overall spending on prescription drugs in private insurance plans.[4]

A strategy that Canadian private insurance plan providers can consider is balancing the increase in costs of biologics by introducing policies to integrate the use of biosimilars into their benefit plans. Private insurers may also have the option of using a Biosimilar First strategy for cost savings, whereby new bio-naïve patients (i.e., patients who have previously never been treated on a biologic) are initially started on biosimilars (when available) and can only access biologics in the case of intolerance or treatment failure from biosimilars.[5]

Another strategy that can be employed is a Product Listing Agreement (PLA), which is an agreement between manufacturers and plan providers to help manage costs.[5,6]

Janssen Inc. is proposing such a PLA strategy for its biologics portfolio, called a Biologics Savings Partnership™ (BSP). The BSP strategy would provide private insurance plans with discounts on the cost of all Janssen biologics to align with the cost of biosimilars, the savings applied to both bio-naïve and bio-experienced patients.

STUDY OBJECTIVE

Janssen engaged RSM Canada to conduct an actuarial analysis of the BSP strategy for private insurance drug plans in Canada. The objective of the study was to assess the cost effectiveness of BSP and industry-wide PLA strategies compared to a Biosimilar First strategy.

* For the purposes of this article, the term biologics will only be used to refer to "innovative" biologics (being a drug that contains a medicinal ingredient not previously authorized in a drug by Health Canada) and "reference" biologics (being a biologic drug already authorized for sale in Canada, which is referenced by the biosimilar seeking an authorization for sale based on a demonstration of similarity to the reference biologic).

BIOLOGICS SAVINGSPartnership™

METHODOLOGY

Biologics and biosimilars included in the analysis were restricted to the following major indications for which the drug products are authorized in Canada: inflammatory bowel disease (Crohn's disease and ulcerative colitis), rheumatoid and psoriatic arthritis, and plaque psoriasis. Twenty-four biologics and biosimilars were included in the analysis, as provided in the table below.

INNOVATOR/REFERENCE BIOLOGICS AND BIOSIMILARS	
ACTEMRA	ORENCIA
BRENZYS (biosimilar)	OTEZLA
CIMZIA	REMICADE®
COSENTYX	RENFLEXIS (biosimilar)
ENBREL	RITUXAN
ENTYVIO	SILIQ
ERELZI (biosimilar)	SIMPONI®
HUMIRA	SKYRIZI
INFLECTRA (biosimilar)	STELARA®
KEVZARA	TALTZ
KINERET	TREMFYA®
OLUMIANT	XELJANZ

The methodology for assessing cost savings included forecasting the biologic and biosimilar spending in the Canadian private insurance market based on product-level, historical claims data gathered by IQVIA and provided by Janssen from January 2016 to July 2019 (Analysis Period). The data was then leveraged, as shown below, in preparation of the analysis:

1. The number of patients in each month was modelled based on an extrapolation of the historical trend of patients in the Analysis Period.
2. The monthly claim cost amount per patient (Cost Per Patient) was calculated by dividing the claims costs by the number of patients for each month in the Analysis Period.
3. The monthly inflationary trends in the Cost Per Patient exhibited in the historical data was linearly extrapolated to estimate future monthly inflationary trends.
4. The Cost Per Patient was then projected over the time horizon by applying the estimated future trends described above to the Cost Per Patient to reflect inflationary effects on drug costs.

The number of new patients was forecasted for the purposes of analyzing the cost savings impact of a Biosimilar First strategy by determining the average number of historical bio-naïve patients and projecting this out into the future and applying retention scale to the individual cohorts of bio-naïve patients entering into the system. The estimation of the retention scale for each drug analyzed is derived from the retention rates by product from the IQVIA database. The retention scale estimated the proportion of patients remaining on the drug based on the database.

The model was developed probabilistically to explicitly and directly consider the inherent risk associated with key input variables. A distribution was used to forecast the future trends in innovator/reference biologics and biosimilars and simulations were run within the model to encapsulate the variance associated with the model. Volatility was introduced for each drug in the following parameters: monthly cost per patient, monthly number of new and existing patients, and the retention scale based on the historical claims data. A model that defines expected values of costs and uncertainties probabilistically is consistent with the guidelines for evaluation of health technology information as provided by Canadian Agency for Drugs and Technologies in Health (CADTH).[7] Taking into consideration the risk and uncertainty directly provides greater insight about the overall cost assessment and also enables more advanced forms of scenario analysis.

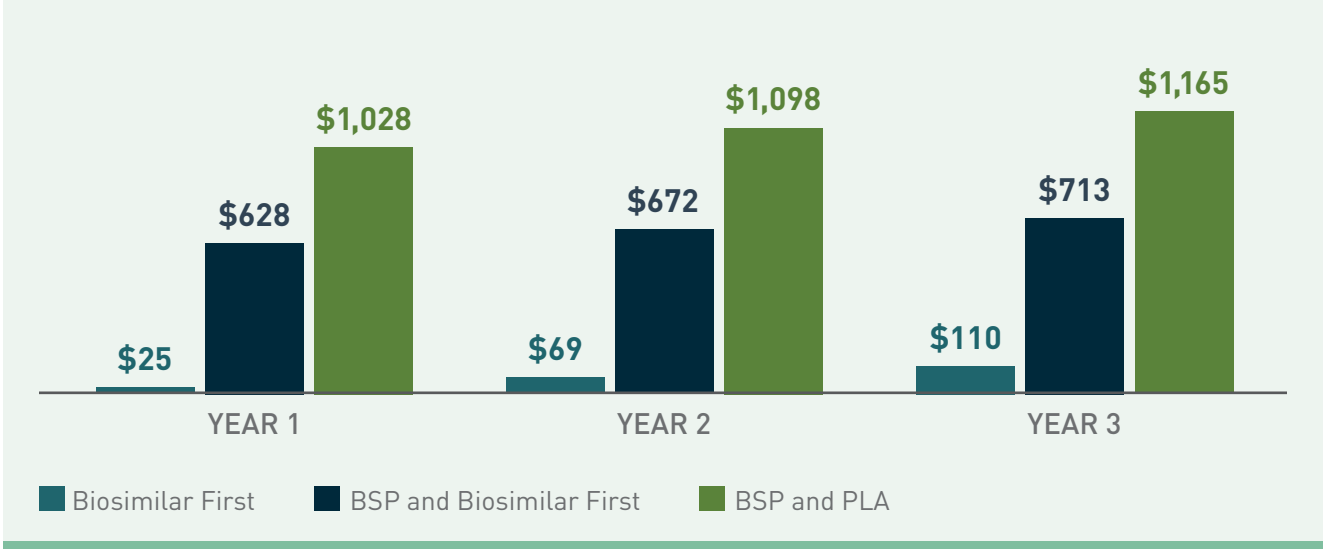
The forecasted market for biologics and biosimilars was then used to create scenarios to model the potential cost saving outcomes from various strategies. Three scenarios modelling cost saving strategies were developed. Cost savings were calculated based on the difference in cost of the three scenarios and cost of the baseline at each month. Cost savings estimates for the three scenarios were then discounted over an 18-month and 36-month (3-year) time horizon to determine the net present value (NPV) of cost savings.

The scenarios are described briefly in the table below.

#	SCENARIO	DESCRIPTION
1	Baseline	• No cost savings strategy applied; and • All scenarios are compared against baseline to establish cost savings.
2	Biosimilar First strategy	• Bio-naïve patients are placed on biosimilars when available; and • Bio-experienced patients continue as before. Cost savings only apply to new bio-naïve patients.
3	BSP and Biosimilar First strategy	• Cost savings from the current use of biosimilars continue. • Cost for bio-naïve and bio-experienced patients on Janssen biologics was discounted such that the annual cost of each biologic is comparable to the annual cost of a biosimilar. For the purposes of this analysis, an amount of $16,000 per patient was identified as the annual cost cap.
4	BSP and PLA strategy	• Cost for bio-naïve and bio-experienced patients on all biologics is discounted such that the annual cost of each biologic is $16,000 per patient, as per the BSP strategy.

KEY FINDINGS

The year-over-year total mean savings to private insurance plans under each scenario are shown in the figure below.



The table below summarizes the total baseline cost and the NPV cost savings at the mean relative to the baseline for the 18-month and 3-year time horizons.

	18-MONTH $ million (% difference)	**3-YEAR** $ million (% difference)
Baseline total cost	$2,859	$5,820
Cost savings from...		
Biosimilar First strategy relative to baseline	$51 (1.8%)	$184 (3.2%)
BSP and Biosimilar First strategy relative to baseline	$922 (32.3%)	$1,864 (32.0%)
BSP and PLA strategy relative to baseline	$1,509 (52.8%)	$3,048 (52.4%)

As illustrated in the results above, the BSP and Biosimilar First strategy is projected to generate significantly higher cost savings to private insurers than the Biosimilar First strategy. In the short term, the BSP and Biosimilar First strategy is estimated to result in 32.3 percent savings to the private insurance spend on biologics and biosimilars relative to the baseline, compared to the 1.8 percent savings from the Biosimilar First strategy alone.

The main reason for this difference is that the savings from the Biosimilar First strategy are derived largely from bio-naïve patients, whereas the savings from the BSP and Biosimilar First strategy are derived from both bio-naïve and bio-experienced patients. Under a Biosimilar First strategy, if a patient fails on a biosimilar, they may move to a more expensive biologic based on historical market shares and retention scales.

The BSP and PLA scenario generates the highest amount of savings at about 52 to 53 percent more savings relative to the baseline. While this scenario does not currently exist on the market today, the intent behind modelling this scenario was to understand the magnitude of savings that could be achieved by private insurers if all biologics manufacturers offered their products at a cost similar to biosimilars.

CONCLUSION

The actuarial analysis found that a combination of the BSP and Biosimilar First approach may lead to substantially more savings compared to the Biosimilar First strategy alone. As such, private payers looking to balance costs may find this strategy to be more effective in terms of managing rising spending on prescription drugs.

However, in interpreting the results, it should be noted that the uncertainty of future changes in the pharmaceutical market is a limitation of the analysis. Significant market fluctuations, based on speculation, of the existing biologics and biosimilars in this market were not incorporated. In addition, the entry of new biologics or biosimilars in the projected time horizons were not considered. For example, when the current patents of innovative biologics expire, several biosimilars are expected to enter the market, which may disrupt the current state market share.

Additionally, the analysis does not take into account the behavioural impact of the different strategies. For instance, there may be changes in the utilization of biologics and biosimilars driven by physician or patient reaction to the cost savings strategies that may impact market share. Other considerations include the impact the BSP and Biosimilar First strategy has on the entry of new biosimilars into the Canadian market.

Given the above, a shorter forecast period (up to 3 years) was selected to support current state market assumptions. A combined BSP and Biosimilar First approach can generate significantly more savings for private insurers while providing physicians and patients the flexibility to choose between biologics and biosimilars. Private insurance plan sponsors should independently review the impact that such an approach could have on their employee insurance plans.

References: 1. Spiridon A. Employers, insurers have role in managing benefits plan sustainability. Benefits Canada, January 25, 2019. Available at: benefitscanada.com/news/employers-insurers-have-role-to-play-in-managing-benefits-plan-sustainability-125151. Accessed August 5, 2020. **2.** Canadian Institute for Health Information. National Health Expenditure Trends, 1975 to 2019: Data tables – Series G. Available at: https://www.cihi.ca/en/national-health-expenditure-trends-1975-to-2019. Accessed August 7, 2020. **3.** Canadian Institute for Health Information. *Prescribed Drug Spending in Canada 2019: A Focus on Public Drug Programs*. Ottawa, ON: CIHI; 2019. **4.** 2019 TELUS Health Drug Data Trends & National Benchmarks. **5.** Lepage S. What to do about BIOSIMILARS? Plan sponsors have new options for cost savings, but switching from reference biologics remains a significant concern. Benefits Canada, January 17, 2017. Available at: https://www.benefitscanada.com/news/what-to-do-about-biosimilars-92284. Accessed November 12, 2020. **6.** Spring 2019. Sun Life Financial's Pharma News. **7.** Guidelines for the economic evaluation of health technologies: Canada. 4th ed. Ottawa: CADTH; March 2017.

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