Canadian Association for Population Therapeutics/ Association Canadienne pour la Thérapeutique des Populations Annual Conference

CAPT ACTP

"Managing risk to improve health outcomes: how to move population health forward in an era of uncertainty"

Breakout # 1
Oral Presentations
Policy & Reimbursement

October 27th 2020
Virtual Platform

Impact of Patented Medicine Prices Review Board new reference countries on drug prices in Canada: A comparison of current and anticipated list prices for top drugs in the country

Chloé Langevin, Université de Montréal

Table of contents

1.

Background

PMPRB Guidelines Modernization

PMPRB Guidelines modernization

The most significant reforms in drug pricing since 1987

Patented Medicine Prices Review Board

Implementation date : January 2021 (Delayed due to COVID-19: July 2021)

Reasons?

- Constantly rising innovative medicine prices
- Canada: 4th position among countries with the highest costs for drug

PMPRB Guidelines modernization

- ✓ Medicines more accessible for Canadian patients
- ✓ Lower spending for Canadian government
- ✓ Lower spending for private insurers

- ✗ Decrease in research and development
- ✗ Delay in access to innovative drugs
- ✗ Layoffs in the pharmaceutical industry

Reference countries

Previous guidelines (Until 2021)

- France
- Germany
- Italy
- UK
- Sweden
- Switzerland
- USA

Modernization

- Australia
- Belgium
- Spain
- France
- Sweden
- UK
- Norway
- Japan
- Netherlands
- Germany
- Italy

Legend:

- No change
- Removed
- Added

Objective

To assess the impact on list prices in Canada of modifying the basket of reference countries used by the PMPRB

2.

Methodology

Selection, Definition and Data analysis

Class selection

Ranking order

15 therapeutic classes were selected from:

Prescribed drug spending in Canada - 2019

Category: Top drug classes by total program spending (TPS)

Active patent

Need for an active patent in order to be under PMPRB jurisdiction (in date of Jan 2020)

Available on Ontario Drug Benefit Formulary

Price availability for the analysis

42 brand name drugs (100 DINs) still under the PMPRB's jurisdiction were analysed

Price definition & Analysis

Canadian price

- Retrieved from the Ontario Drug Benefit Formulary (in date of Jan 2020)

International price

- Retrieved from each country's drug price platform (from Jan to March 2020)
- Converted to Canadian Dollar (CAD) following PMPRB guidelines

Data Analysis

- Estimated impact was calculated as the difference between current Canadian list prices and projected median international prices under the new regime

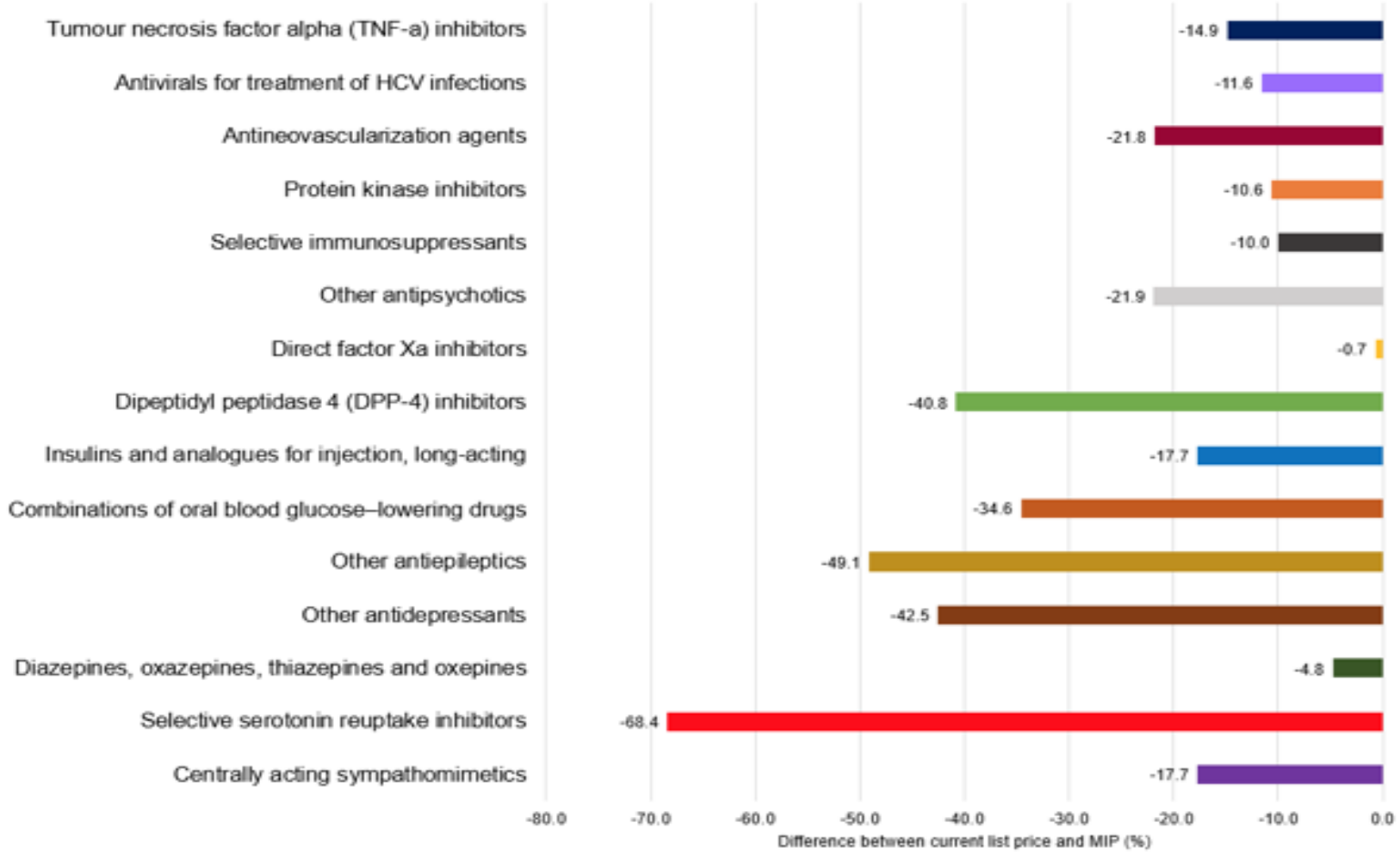
3.

Results & Discussion

Impact of the reform: Achieved its goal ?

Variations between classes

Difference between current list price and MIP per therapeutic classes (in %)



General decrease in prices is observed for all therapeutic classes

- Variability was observed across classes, but expected reductions are as high as 68.4%

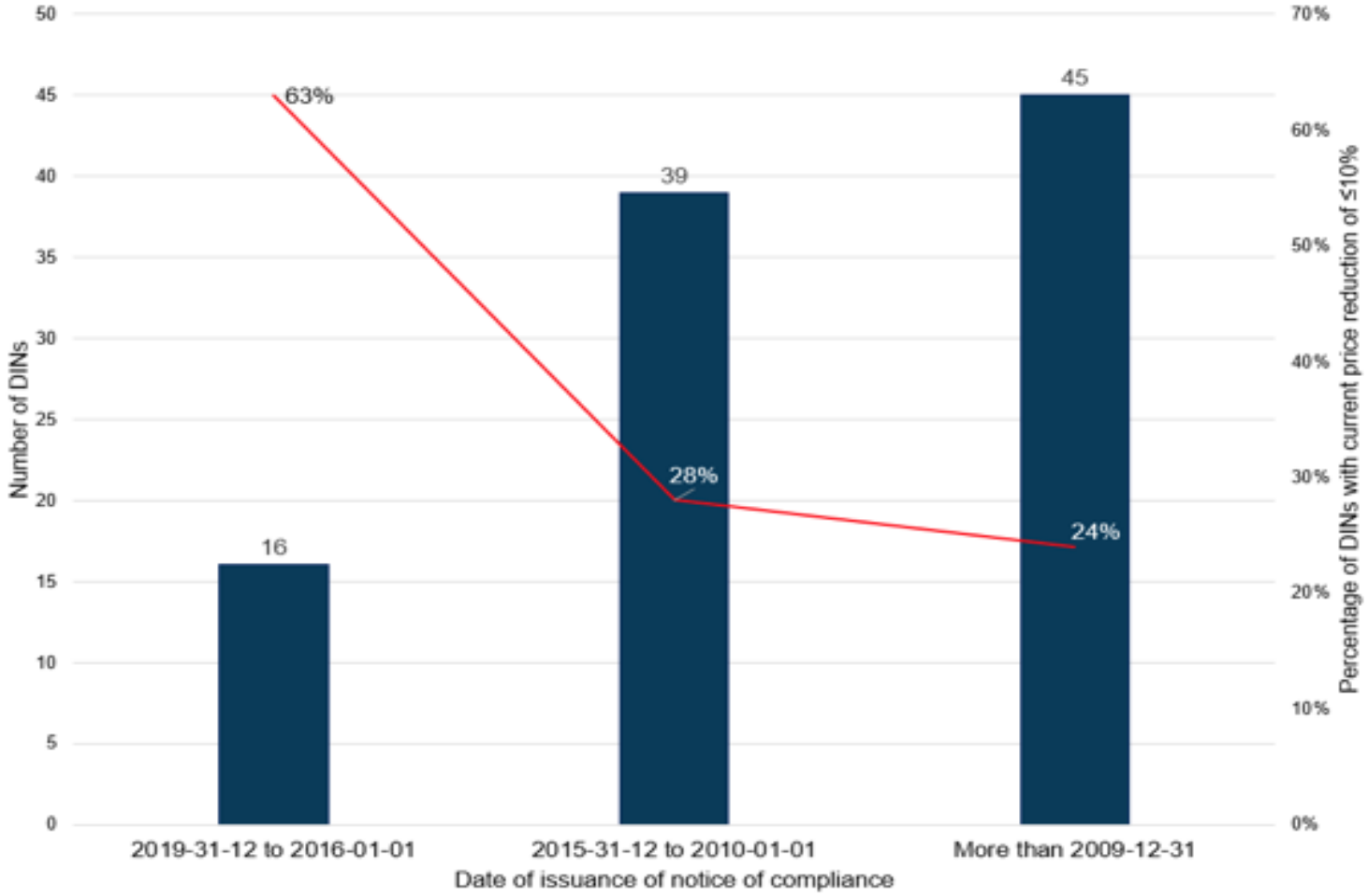
Global analysis

42 brand name drugs (100 DINs) still under the PMPRB's jurisdiction were analysed:

An overall weighted average list price **reduction of 28.4%** is expected with the modification of reference countries

Additional factor influencing drug pricing

Impact of NOC date of issuance on the difference between current list price and MIP



Innovative medicines that have received an NOC in the past 5 years show price reduction of less than 10% in 63% of cases, compared to 28% for medicines that received NOC between 5 and 10 years

Study limitations

- Prices published by public drug insurance plans in Canada are not the one actually paid by public insurers
- Does not consider other measures included in the new regulation and, as such, likely underestimates the total anticipated impact of the reform on list prices
- Medicines are not available in all reference countries
- List prices in Canada may vary from Ontario list price

4.
Conclusion

Impact of the PMPRB reform

The pharmaceutical landscape will undergo drastic changes due to the implementation of the new PMPRB guidelines

<u>Impact of the modification of the comparator countries:</u>

- Overall reduction in drug prices of **28.4 % for the 15 Top drug classes**

The objective to make drugs more affordable will be achieved but at what cost ?

At the expense of Canadian patients

Thank you!

Questions?

Chloé Langevin

chloe.langevin@umontreal.ca

OCTOBER
2020

A retrospective view on plan sustainability in 2019 from a large Canadian private payer

Authors: Sarah Nguyen, Anjila Arora, Jessica Hayes, Jade Doobay

Sun Life

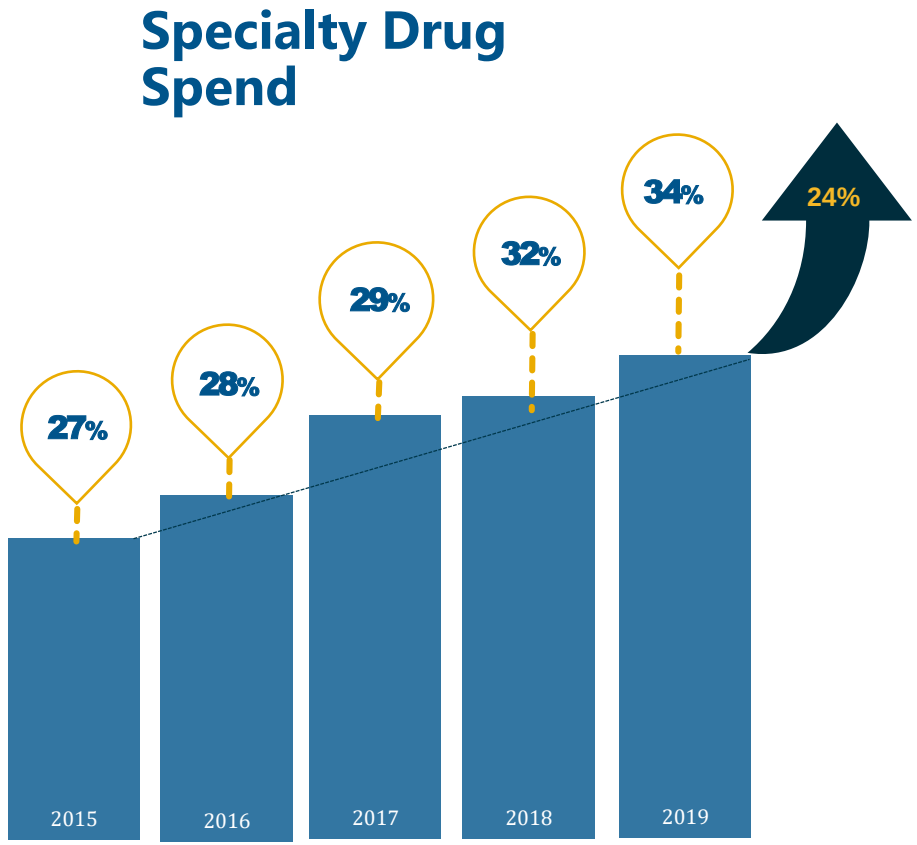
Life's brighter under the sun

Background

In 2019, drug spend continued to increase at an unsustainable rate compared to the rate of inflation.

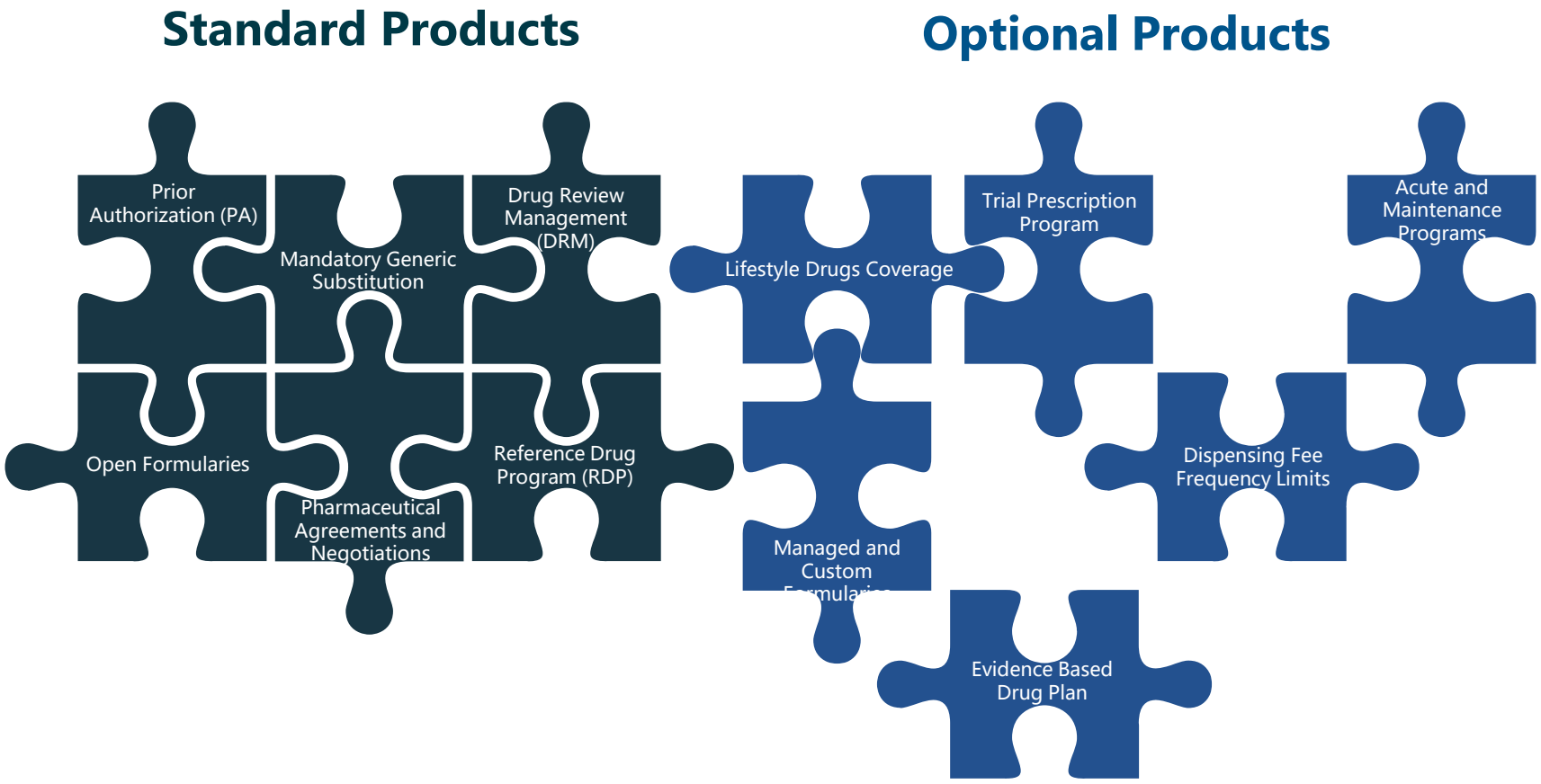
Factors affecting plan sustainability:

- ✓ The number of approvals for specialty drugs
- ✓ The cost of specialty drugs



Reference:
Pharma Snapshot 2019, Sun Life, 2020

Cost Containment Strategies



Results

Year	Inflation Benchmark	Actual % Growth Growth (YOY)
2014	2.0%	4.6%
2015	1.1%	8.7%
2016	1.4%	5.6%
2017	1.6%	5.7%
2018	2.3%	2.3%
2019	1.9%	7.9%
Projected 2020	2.0%	3.9%
Projected 2021	2.0%	4.5%
Projected 2022	2.0%	4.3%

Reference:
[1] *Sun Life data, 2019*
[2] *Consumer Price Index (CPI), 2020*

Thank you

Sun Life

Life's brighter under the sun

Reimbursement recommendations of conditionally-approved cancer drugs in Canada

Emily Arthur[1,2], Robert Milenkovski[2], Graeme Ball[2], John-Paul Marino[2]

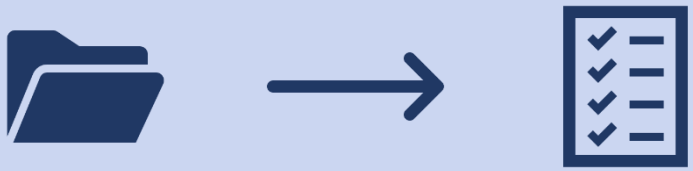
[1]University of Guelph
[2]Gilead Sciences Canada

Conflict of Interest

- I am a student at the University of Guelph and was employed by Gilead Sciences at the time this analysis was performed.
- There are no other conflicts of interest.

Rationale

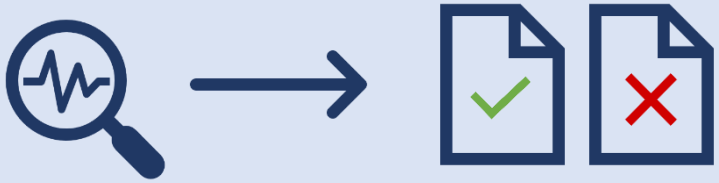
Health Canada Santé Canada



NOC

NOC/c

CADTH | pCODR

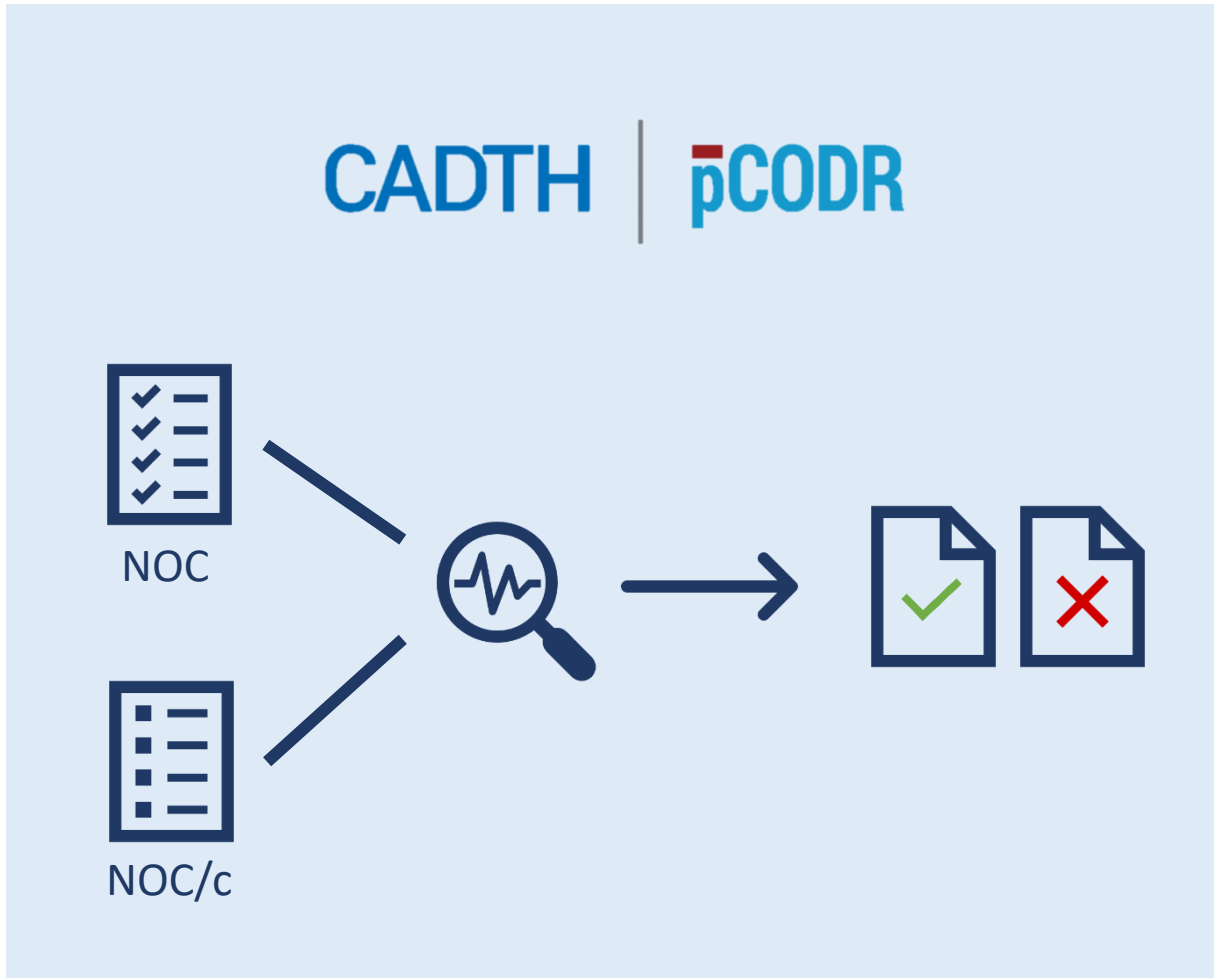


Payors

Objectives

- In a single analysis, compare NOC and NOC/c pCODR files based on:
    1. Likelihood of positive outcome
    2. Time to recommendation
    3. Reason for recommendation
- Compare results with previous analyses

Understand how the pCODR review process manages drugs approved through the NOC/c pathway compared to the traditional NOC pathway

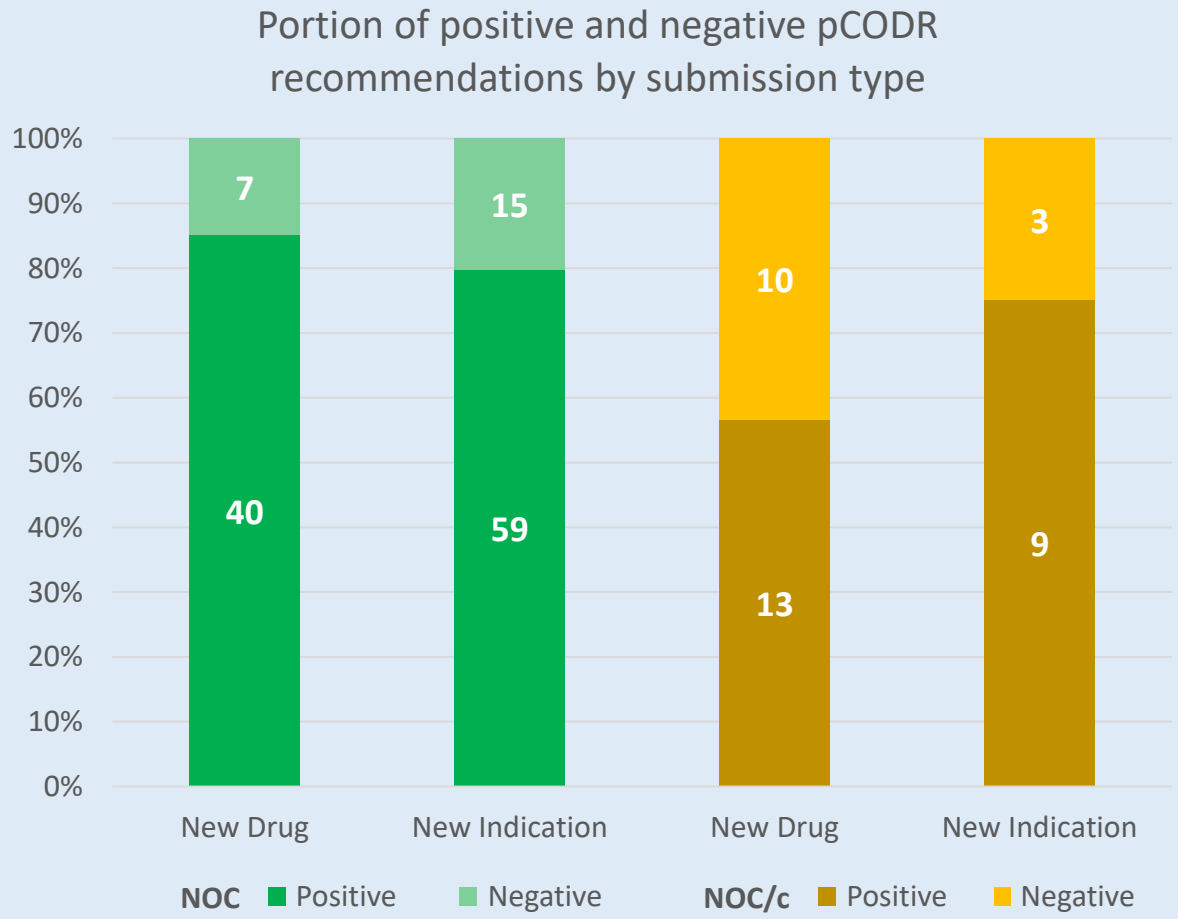


Methodology

1. **Search** Health Canada and pCODR databases to identify NOC/c files
2. **Capture** file data based on timing and reasoning for positive and negative outcomes
3. **Connect** data from Health Canada and pCODR to identify patterns
4. **Analyze** the impact of Health Canada pathway on pCODR outcome

Focused on pCODR files associated with a New Drug or New Indication ("unique drug-indication pairings").

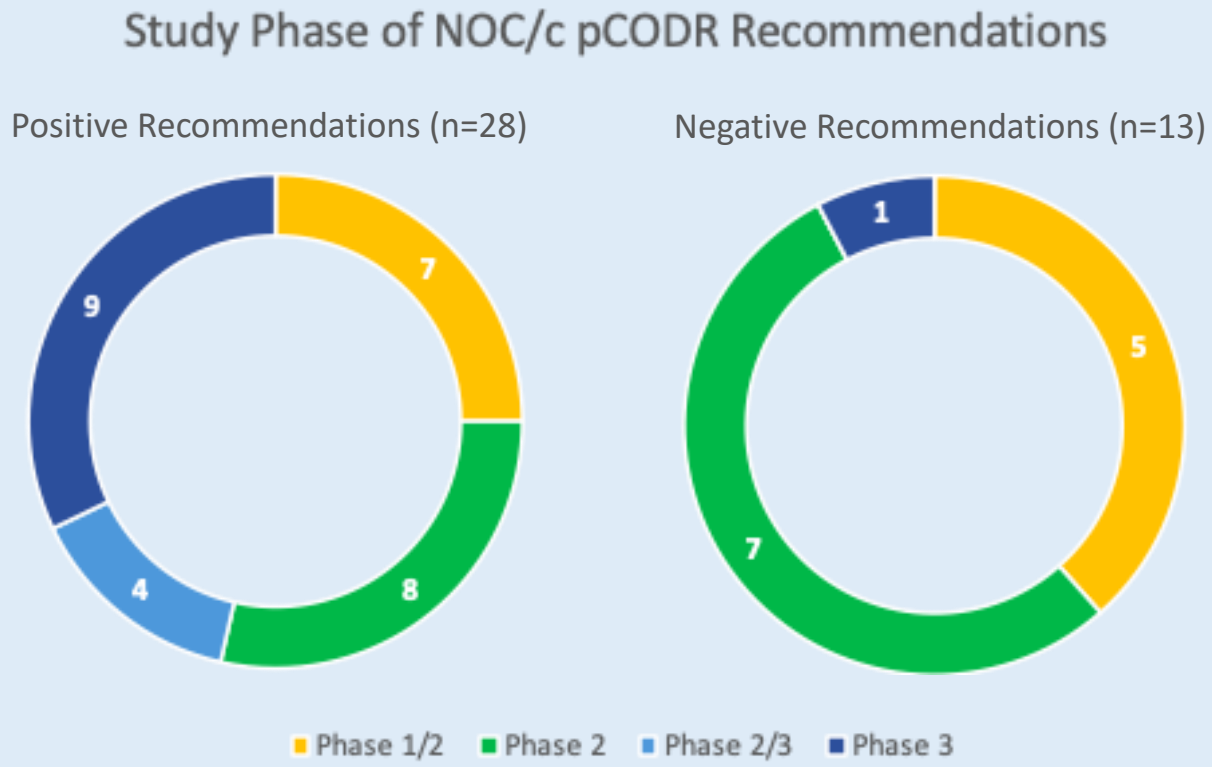
Results



% Positive	NOC	NOC/c	p
New Drug	85.1	56.5	0.009
New Indication	79.7	75.0	0.709
All Unique Submissions	81.8	62.9	0.018

New Drug pCODR files reviewed under the NOC/c pathway were significantly less likely to receive a positive reimbursement recommendation

Results: NOC/c Files



Clinical uncertainty was the primary rationale for NOC/c files receiving negative recommendations.

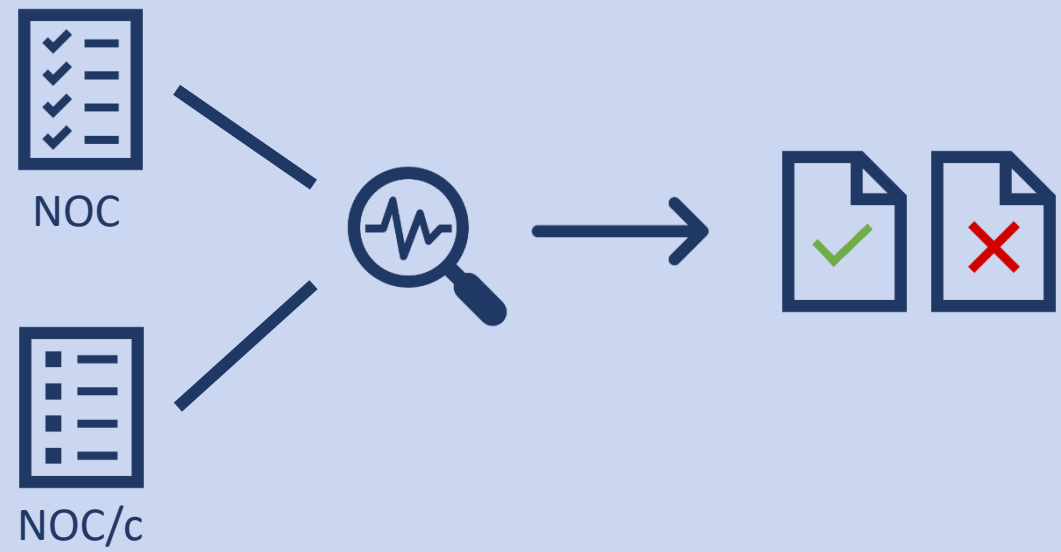
Resubmissions leveraging additional trial data were often recommended.

NOC/c files submitted to pCODR with phase 2/3 or 3 study data were about 6 times more likely to receive a positive recommendation than those with phase 1/2 or 2 data.

Discussion

- The most common condition given to NOC/c files was that the manufacturer continue to gather additional clinical data.
- These files were then submitted to pCODR and evaluated under the same pathway as traditional NOC files.
- Negative pCODR recommendations for NOC/c files often cited data immaturity as a rationale and suggested resubmitting with more mature data.
- Alternative reimbursement models may be needed to ensure temporary access for patients while additional data is reviewed by pCODR.

The NOC/c pathway was designed to enable accelerated access to drugs with promising clinical data.



Conclusion

- ***The NOC/c pathway was designed to enable accelerated access to drugs with promising clinical data.***
- ***New Drug pCODR files reviewed under the NOC/c pathway were significantly less likely to receive a positive reimbursement recommendation***
- ***Clinical uncertainty was the primary rationale for NOC/c files receiving negative recommendations.***
- ***Resubmissions leveraging additional trial data were often recommended.***
- ***NOC/c files submitted to pCODR with phase 2/3 or 3 study data were about 6 times more likely to receive a positive recommendation than those with phase 1/2 or 2 data.***

Acknowledgements

- I would like to express my gratitude to the Market Access team at Gilead Sciences Canada, specifically Robert Milenkovski, Graeme Ball, and John-Paul Marino, for their support of this analysis.

Case study to explore patient-level impact of adoption of subsequent entry biologic anti-TNF medicines

Dylan Lamb-Palmer

Dylan Lamb-Palmer PDCI Market Access

Dylan Lamb-Palmer Manager, Pricing and Data Analytics

Working with the PDCI's Data Innovation team, Dylan helps develop and maintain PDCI's data analytics services including PDCI's Market Access Toolkit, national public claims data, private claims data, and price trends. Dylan leverages this experience to assist with PDCI's whitepaper publications.

Presentation Agenda

1. **Background and Objective**
2. **Methods**
3. **Results**
   - Market share of biosimilars versus brand in Canada
   - etanercept *versus* infliximab biosimilar uptake
   - British Columbia *versus* Ontario biosimilar uptake
   - Evolution of initiation *versus* switching rates
4. **Discussion**
5. **Conclusion**

Background & Objective

The objective of this analysis was to explore the patient-level impact of recent adoption efforts on SEB initiation of anti-TNF medicines in the Canadian Private market.

Canada has the second highest per capita biologic spending among OECD countries. Subsequent entry biologic (SEB) adoption remains low compared to other countries despite the Canadian biosimilar industry, Health Technology Assessment Agencies, and payers working to enhance biosimilar adoption.

Anti-Tumour necrosis factor (TNF) medicines are a high cost burden for private payers and were an early class of biologics with available SEBs in Canada.

Methods

Overview: The population of interest was patients with at least one claim for **etanercept** or **infliximab** between January 2012 and March 31, 2020. Descriptive statistics (mean, standard-deviation [SD]) were used to describe trends in biologic and SEB initiation and switching. Subgroup analyses were conducted according to age, province, and gender.

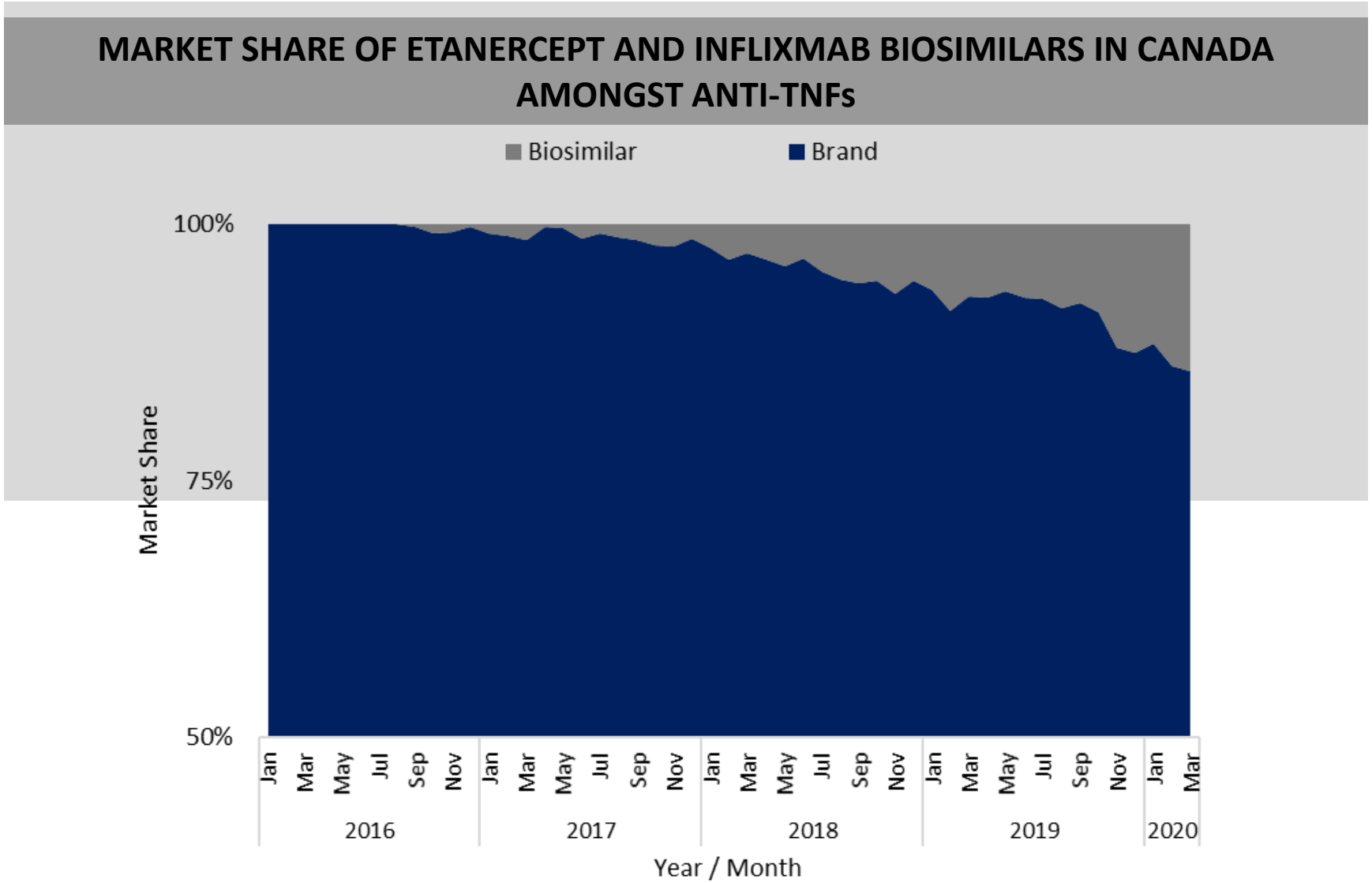
Data Source: This analysis was conducted using PDCI's Private Claims Database, representing an average annual sample of 1.6 million covered lives.

Results: Data Summary

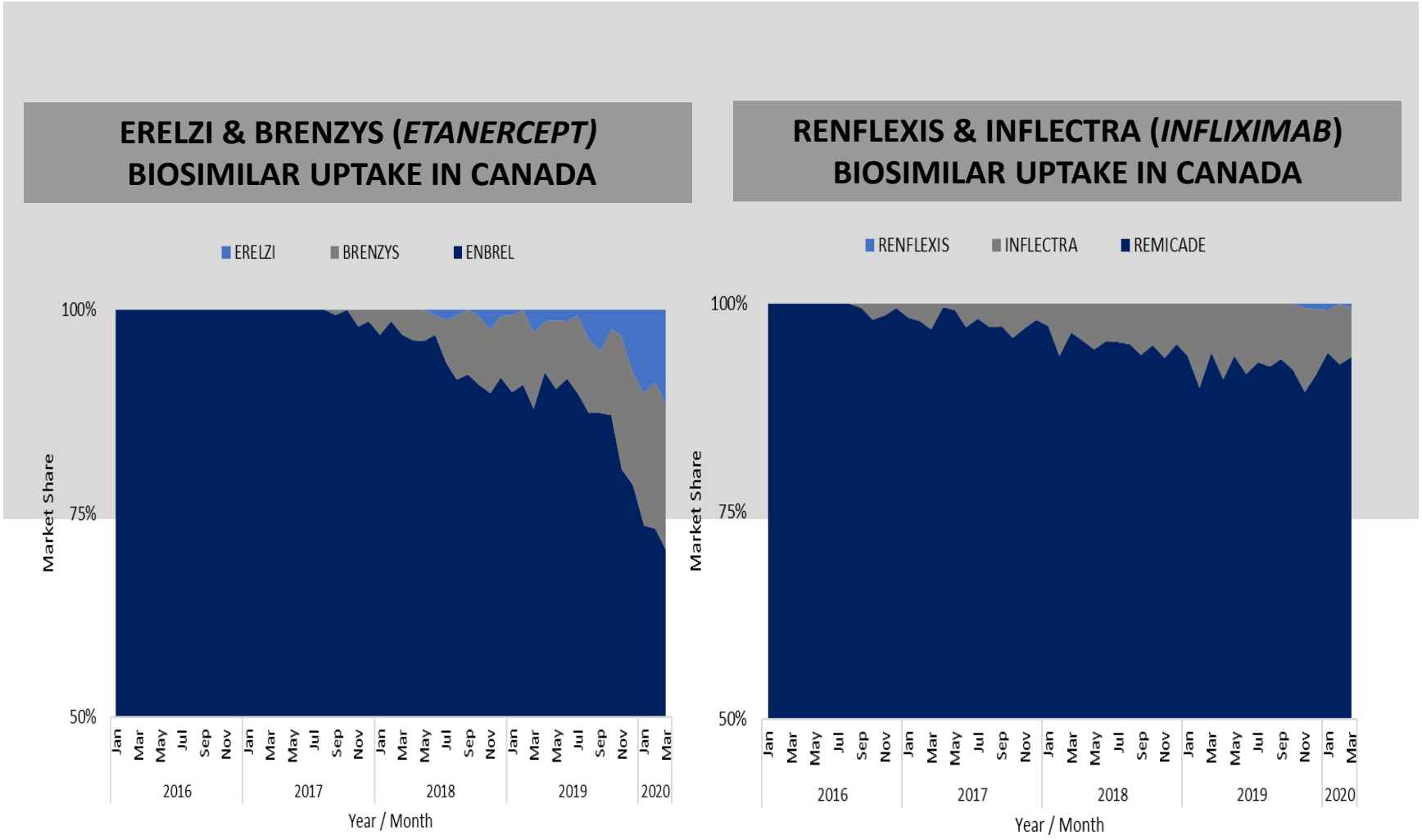
Of the 2,953 patients that were identified for this analysis:

- **164** received a biosimilar,
- **48%** (n=79) of initiations were in the most recent 12-months (April 1, 2019 – March 31, 2020)
- 30 **(18%)** biosimilar recipients were switched from the innovator with 26 (87%) in the most recent six-months
- The mean patient age when initiated with etanercept was **47.8** (SD=13.9) years:
  - **44.7%** were male
- The mean patient age when initiated with infliximab was **38.5 (**SD=14.3) years:
  - **51.5%** were male

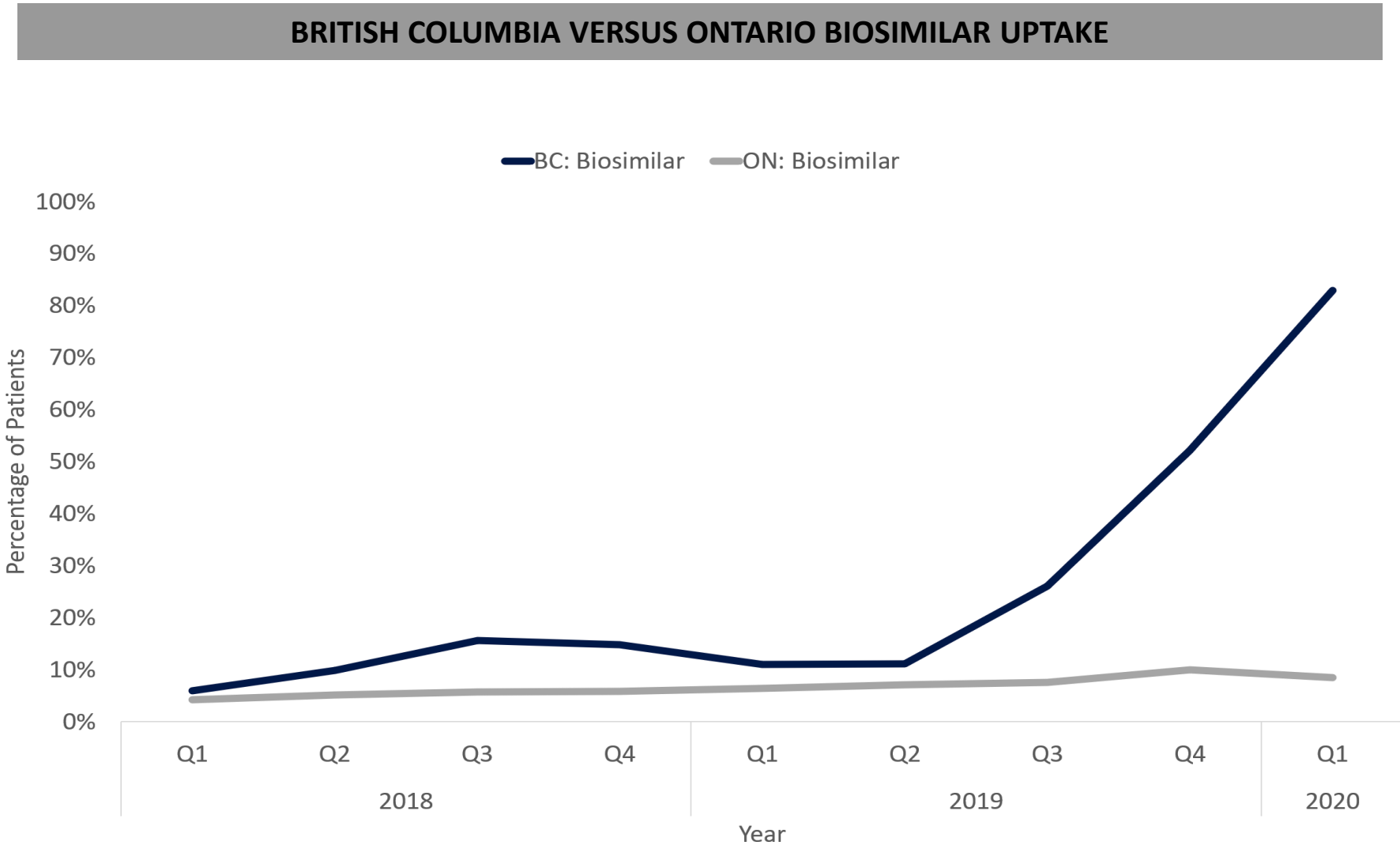
Results: National biosimilar uptake



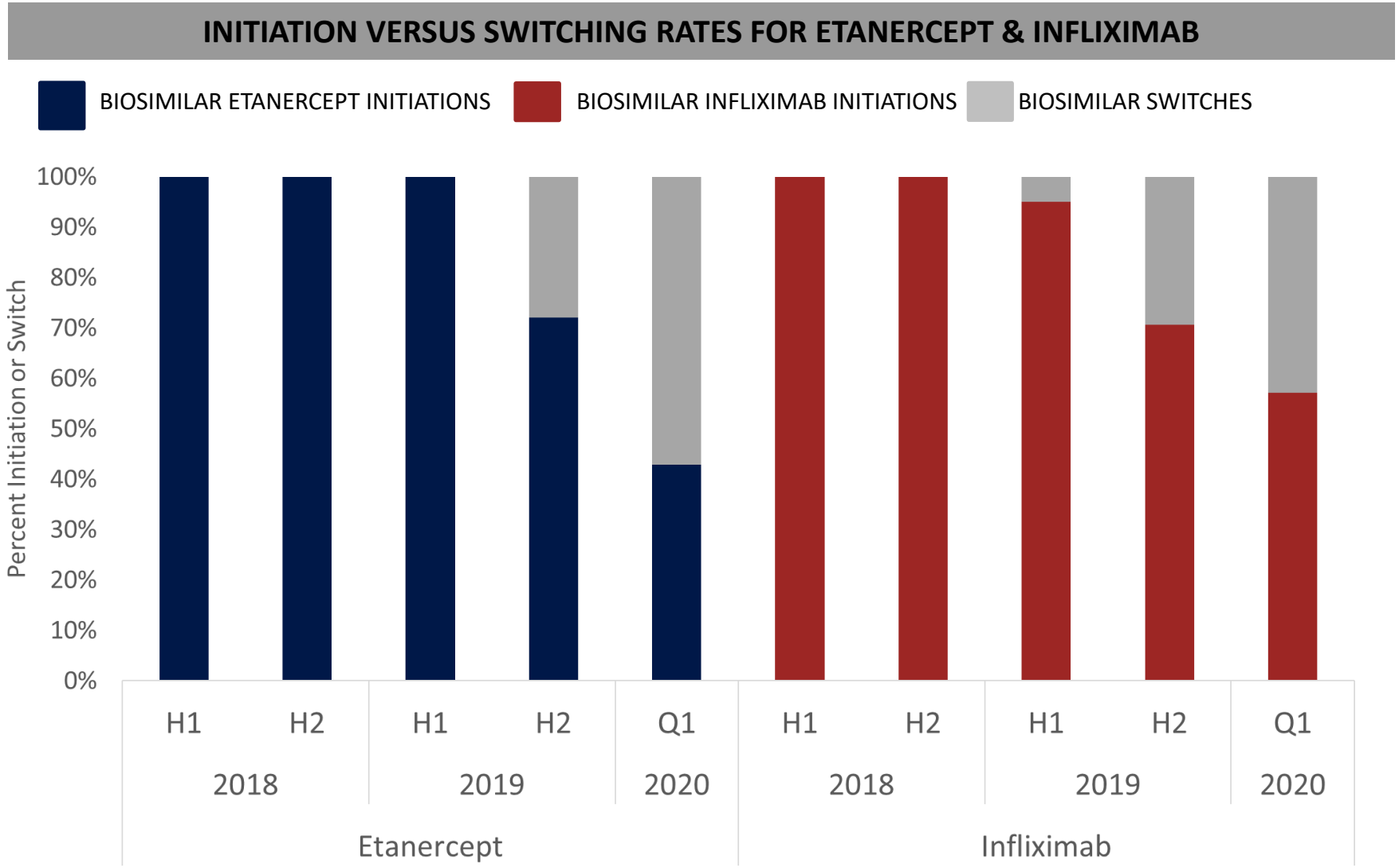
Results: etanercept *versus* infliximab Biosimilar Uptake (National)



Results: British Columbia Increasing in Biosimilar Uptake



Results: etanercept and infliximab Starts Increasing in Proportion of Switches (National)



Discussion & Insights

- Biosimilar uptake remains low in the Canadian private market.
- Infliximab uptake remained low in 2019 and 2020; etanercept uptake increased from of 12% in 2019 to 28% in 2020.
- Increasing biosimilar uptake is seen in the last 18 months and is driven by uptake in British Columbia (BC).
- Although early biosimilar uptake was limited to new patient starts, our analysis found recent increases in switching from innovator to biosimilars in the private market.
- Subsequent to public policy initiatives put in place in May 2019, BC private claims showed increased uptake of infliximab and etanercept biosimilars compared to other provinces[1]. The increase in uptake aligns with implementation of BC Pharmacare's Phase I and Phase II biosimilar programs.[2]
- BC's adoption of biosimilars outpaced other provinces including Ontario.
- A similar public initiative to enhance biosimilar adoption in Alberta was delayed due to pandemic considerations.[3] Similar initiatives were anticipated in Ontario but have not been announced.[4] Private effects in these regions were not observed.
- Public reimbursement policy to switch patients from the originator to biosimilar infliximab may increase private market switching.

1. Government, B. C. (2020). Biosimilars Initiative for Patients. Retrieved from British Columbia: https://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/what-we-cover/drug-coverage/biosimilars-initiative-patients#1
2. British Columbia Pharmacare. (n.d.) Biosimilars Initiative for Prescribers. Retrieved from British Columbia: https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/biosimilars-initiative-prescribers
3. Government, A. (2020). Biosimilar drugs. Retrieved from Alberta: https://www.alberta.ca/biosimilar-drugs.aspx
4. Saba, R. (2020, March 5). Ontario is considering funding cheaper versions of biologic drugs. Patients in B.C. urge caution. Retrieved from The Star: https://www.thestar.com/news/canada/2020/03/05/ontario-is-considering-funding-cheaper-versions-of-biologic-drugs-patients-in-bc-urge-caution.html

Conclusion

While this analysis found recent increases in switching from the innovator to biosimilars in the private market, early uptake of biosimilars was limited to new patient starts. Further research is necessary to explore the impact of switching on patients in the Canadian private insured setting.

Thank you