

CADTH Health Technology Review

Utilization of Old- Versus New-Generation Biologics for Plaque Psoriasis for Public and Private Payers in Canada

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Abbreviations

CIHI	Canadian Institute for Health Information
CLHIA	Canadian Life and Health Insurance Association
FPT	federal, provincial, and territorial
IL	interleukin
LoE	loss of exclusivity
NOC	Notice of Compliance
NPDUIS	National Prescription Drug Utilization Information System
PASI	Psoriasis Area and Severity Index
pCPA	pan-Canadian Pharmaceutical Alliance
PLA	product listing agreement
PsO	plaque psoriasis
QALY	quality-adjusted life-year
TNF	tumour necrosis factor

Key Messages

- **Issue:** Recent health technology reviews by CADTH, including a national [Environmental Scan](#) of biologics for PsO across public drug plans and a [review](#) of the clinical evidence on the comparative effectiveness of biologics for PsO, have suggested that the appropriate use of biologics for the treatment of plaque psoriasis (PsO) may favour new-generation biologics (i.e., anti-interleukin [IL]-17 and anti-IL-23 inhibitors) over old-generation biologics (i.e., anti-tumour necrosis factor and anti-IL-12/23 biologics). Specifically, these reviews found:
 - New-generation biologics for PsO consistently demonstrated greater efficacy compared to old-generation biologics in recent head-to-head trials (e.g., AMAGINE-2 and AMAGINE-3, FIXTURE, IMMvent, NAVIGATE, UltIMMA-1 and UltIMMA-2, UNCOVER-2 and UNCOVER-3, and VOYAGE-1 and VOYAGE-2).
 - Formulary listings of the old-generation biologics mostly predate any pan-Canadian Pharmaceutical Alliance (pCPA) agreements, which increases the likelihood of fewer product listing agreements (PLAs) with public payers for these drugs, whereas all new-generation biologics have all undergone pCPA negotiations. For private payer formulary listings, PLAs are not publicly disclosed although, according to the Canadian Life and Health Insurance Association (CLHIA), they are likely to occur.
 - Old-generation biologics have reached the expiration of their exclusivity periods (i.e., time when an originator biologic is protected from biosimilar competition), whereas all new-generation biologics currently have active exclusivity status.
- **Approach:** A national utilization study was conducted to assess the utilization patterns of old- versus new-generation biologics in PsO for both public payers (using Canadian Institute for Health Information [CIHI] data) and private payers (using Reformulary and CLHIA data), prescribing patterns (market share and average costs) for old- versus new-generation biologics for both public and private insurance among new and existing users, and expenditures (excluding PLAs) on biologics for PsO after LoE by public and private payers.
- **Findings:**
 - Although new-generation biologics in PsO are associated with greater efficacy, approximately 44% of patients newly initiating a biologic across public and private drug plans in Canada were prescribed an old-generation biologic in 2020.
 - Average annual cost per new patient was typically higher for old-generation originator biologics (range = \$11,645 to \$16,047) versus new-generation biologics (range = \$8,303 to \$15,229) across public payers. Ustekinumab is associated with the highest cost estimate among new patients within public drug plans and, despite having expired exclusivity status, does not have a marketed biosimilar option available.
 - Canadian taxpayers (i.e., public and private drug spending) have spent up to \$9 billion (gross expenditures) on all claims for originator biologics indicated for PsO that have lost exclusivity between 2016 and 2020. To put this in perspective, analyses of data from the National Prescription Drug Utilization Information System (NPDUIS) revealed that, in Canada, spending on oncology drugs in the latest reported year (2019) was \$3.9 billion and spending on the top 50 drugs in the 2019–2020 fiscal year was \$4.3 billion.
- **Implications for policy-makers:** Given the potential for improved efficacy and lower costs of new-generation biologics, the promotion of the appropriate use of biologics in PsO should be considered by payers.

Executive Summary

Background: Plaque psoriasis (PsO) is an immune-mediated skin condition characterized by red, scaly, raised patches that frequently produce itching, pain, and lowered quality of life. Patients with PsO who do not respond to first-line treatment are often treated with biologics that target cytokines, such as tumour necrosis factor (TNF), interleukin (IL) 12/23, IL-17, or IL-23. There are 11 total biologics indicated for PsO approved in Canada, which can be classified as old-generation molecules (i.e., anti-TNF and anti-IL 12/23 biologics) or new-generation drugs (i.e., anti-IL-17 and anti-IL-23 inhibitors). All old-generation biologics have expired exclusivity status (i.e., time when an originator biologic is protected from biosimilar competition); however, biosimilar versions of these drugs have launched several years after their eligibility or do not even currently have a biosimilar. Moreover, the reimbursement of the old-generation biologics mostly predated any pan-Canadian Pharmaceutical Alliance (pCPA) agreements, which increases the likelihood of fewer product listing agreements (PLAs) with public payers. For private payers, PLAs are not publicly disclosed although, according to the Canadian Life and Health Insurance Association (CLHIA), are likely to occur. Recently, new-generation biologics with active exclusivity status have all undergone pCPA negotiations. Additionally, biosimilar competition has not reduced expenditures to the degree that policy-makers had hoped for; therefore, there may be a significant opportunity cost paid by society for originator biologics after loss of exclusivity (LoE). Given these dynamics, a utilization study was conducted to assess the current use of biologics in PsO across Canada, which included both public and private drug plans.

Policy issue: The prevalence of PsO in Canada is increasing; therefore, the utilization of and spending on PsO biologics will also continue to rise. New evidence has emerged demonstrating the greater efficacy of the new-generation biologics versus the old-generation molecules in PsO. Given this new evidence, the fact that the old-generation molecules have lost exclusivity, and under the presumption that the new-generation biologics are appropriately priced for public payers given pCPA involvement, there is rationale for federal, provincial, and territorial (FPT) drug plans to evaluate the utilization patterns of and expenditures on these therapies within their drug plans. Additionally, because exclusivity of biologics applies to all payers, expenditures post-LoE should be considered a national issue and applies to private insurance as well.

Objective: Public and private drug claims data were analyzed to determine the utilization patterns and cost of old- and new-generation biologics indicated for PsO to estimate the gross expenditures on old-generation biologics post-LoE (i.e., opportunity cost or welfare losses).

Approach: Public claims data were extracted from the National Prescription Drug Utilization Information System (NPDUIS) database. Private claims data were extracted from 2 sources: the Reformulary Group's prescription drug claims database and private insurers who are part of CLHIA. Because biologics are used to treat numerous indications, drug-marker algorithms, based on existing and previous drug use, were applied to identify patients receiving treatment for PsO. The number of claimants, claims, and cost data were collected and stratified by calendar year, jurisdiction, chemical, and type of biologic when feasible. To examine utilization patterns over time, the market share (percentage of claimants) was estimated for each biologic from 2018 to 2020. To evaluate costs, the average cost of utilization per claimant for each drug was calculated. To determine the gross expenditures for old-generation biologics after LoE, total submitted costs on claims made for each old-generation originator biologic

were summed from 2016 (the earliest LoE date for an originator biologic) to 2020. Cost data did not reflect PLAs between drug plans and manufacturers.

Major findings: Although there has been a year-to-year increase in the use of new-generation biologics over time, in 2020, approximately 25% of patients across public drug plans and 44% of patients across both public and private drug plans newly initiating a biologic for PsO (i.e., first claim for a biologic) were prescribed an old-generation biologic. Within the public drug plans, there was variability across jurisdictions, as Manitoba, Alberta, and Saskatchewan exhibited relatively greater use of the new-generation biologics in 2020 (100%, 90.7%, and 88.7%, respectively). The average annual cost per patient was typically higher for old-generation originator biologics (range = \$11,645 to \$16,047) versus new-generation biologics (range = \$8,303 to \$15,229) across public payers. The biologic with the highest average annual cost per patient among new patients across public drug plans was ustekinumab (\$16,047), which despite having expired exclusivity status, does not have a marketed biosimilar option available. In terms of gross expenditures beyond LoE, it is estimated that people living in Canada (across both public and private drug plans) have spent up to \$9 billion on all claims for originator biologics indicated for PsO that have lost exclusivity between 2016 and 2020. This signals a potential loss value because these expenditures could have been reduced with the use of biosimilars or reallocated to more efficacious treatments (i.e., the new-generation biologics).

Implications for policy-makers: Despite access to new-generation biologics with more favourable efficacy, old-generation biologics are still used significantly in new patients with PsO across Canada. Given the potential for improved efficacy and lower costs of new-generation biologics, the promotion of the appropriate use of biologics in PsO should be considered by payers. Jurisdictions with a biologic tiering policy (i.e., Manitoba and Alberta) have the highest rate of prescribing of new-generation drugs, which suggests a change in reimbursement criteria by payers may promote their use. The annual cost per patient tends to be typically higher for old-generation originator biologics across public payers and, despite LoE, some of these drugs do not currently have a biosimilar version available (i.e., ustekinumab and certolizumab pegol). This cost difference may be even greater if net prices were assessed because the new-generation biologics underwent pCPA negotiations with public payers. Global agreements and a shorter data protection period in Canada may be driving this expenditure post-LoE. Physician prescribing patterns may also reflect that there are no recent Canadian treatment guidelines on the management of patients with PsO. Payers should consider how to get better value from these drugs given the scale of the expenditures and there should be more focus on addressing formulary management in this area.

Context

Plaque Psoriasis

PsO is an immune-mediated skin condition characterized by red, scaly, raised patches that frequently produce itching, pain, and lowered quality of life.^{1,2} PsO is also recognized as a multi-systemic disease because it is associated with serious comorbidities.³ PsO is common in Canada, with 2.5% of adults in Ontario diagnosed with this disease; estimates show that its prevalence has been steadily increasing over the past decade because of a combination of population aging, population growth, and increasing life expectancy.⁴ First-line treatments

include phototherapy, topical creams, and oral systemic anti-inflammatory medications.¹ Severe disease that does not respond to first-line treatment is treated with biologics that target cytokines, such as TNF, IL-12/23, IL-17, or IL-23.² The economic burden of moderate to severe PsO in Canada has been estimated to be \$1.7 billion (95% confidence interval, \$0.8 billion to \$2.6 billion) annually, with 43% of this cost attributed to productivity loss.⁵

Old- and New-Generation Biologics

Biologics are among the highest and fastest-growing drug expenditures for public drug plans.⁶ An analysis based on IQVIA's MIDAS Database found that sales of biologics in Canada has tripled over the past decade (from \$3.3 billion in 2011 to \$10.0 billion in 2020) and that Canada was ranked third and fourth among all countries in the Organization for Economic Co-operation and Development (OECD) in 2020 for biologic share of all pharmaceutical sales nationally (biologics accounted for one-third of all pharmaceutical sales in the country in 2020) and biologic spending per capita, respectively.⁷ This same analysis identified that infliximab and adalimumab were the 2 top-selling biologics in Canada, although biosimilar versions of these drugs accounted for 20% and 0%, respectively, of each biologic's market share in 2020.⁷ Due to differences in biosimilar policies across jurisdictions, biosimilar uptake varies across provinces, with British Columbia being the earliest adopter of biosimilar switching initiatives, particularly for 3 biologics : infliximab, etanercept, and insulin glargine. If the national uptake of biosimilars for these 3 drugs followed the same trends as in British Columbia, it is estimated that Canada would have saved \$1.1 billion from 2020 to 2021.⁷

Biologic therapies for psoriasis can be classified according to their Health Canada Notice of Compliance (NOC) and mechanism of action, with the old-generation molecules including anti-TNF and anti-IL 12/23 biologics with a first NOC before 2010 and the new-generation drugs including the anti-IL-17 and anti-IL-23 inhibitors with a first NOC in 2015 or later. All old-generation biologics have expired exclusivity status (defined here as expiry of data protection, expiry of patent protection, or regulatory approval of a biosimilar version); however, biosimilar versions of etanercept, infliximab, and adalimumab have launched several years after their eligibility (e.g., approximately 3 years for adalimumab and 4 years for etanercept) and 2 other old-generation molecules (i.e., ustekinumab and certolizumab pegol) do not currently have a biosimilar.⁸ Moreover, reimbursement of the originator versions of these biologics mostly predated any pCPA agreements, thus increasing the likelihood of fewer PLAs with public payers. However, according to the CLHIA, many private insurers have acquired PLAs for the old-generation biologics over time. Recently, new-generation biologics with active exclusivity status have been reimbursed across Canada and have undergone pCPA negotiations (although some failed to reach agreements).⁸

A previous CADTH review identified 8 network meta-analyses that consistently demonstrated more favourable skin clearance outcomes (i.e., achieving 90% and 100% skin clearance) with the new-generation biologics relative to the old-generation molecules.⁹ The new-generation biologics have also been found to be more cost-effective in multiple health economic evaluations.¹⁰ A study conducted in Germany found that secukinumab, an anti-IL17A inhibitor, had the lowest cost per Psoriasis Area and Severity Index (PASI) 90 responder compared with the old-generation biologics ustekinumab, adalimumab, infliximab, and etanercept.¹¹ Studies conducted in Japan also concluded that secukinumab was cost-effective relative to old-generation biologics.^{12,13} More specifically, in a study by Igarashi et al., the authors found that secukinumab resulted in the most quality-adjusted life-years (QALYs) gained, and the resulting incremental cost-effectiveness ratios showed that it dominated both infliximab and ustekinumab and could be considered cost-effective, depending on the

willingness-to-pay threshold, versus adalimumab with an incremental cost-effectiveness ratio of ¥8,418,222 (approximately \$92,400) per QALY gained (secukinumab generated greater QALYs at a higher cost versus adalimumab).¹² In a study on biologic drugs approved for PsO in Italy, Ravasio et al. showed that ixekizumab and secukinumab resulted in the lowest cost per PASI responder (PASI 75, 90, or 100) relative to adalimumab, etanercept, and ustekinumab.¹⁴ Studies conducted in the US also determined that IL-17 biologics (i.e., brodalumab, ixekizumab, and secukinumab) were cost-effective strategies for patients with PsO.^{10,15-17} Hendrix et al. found that IL-17 inhibitors resulted in the greatest QALYs relative to old-generation biologics and that initial treatment with 1 of the IL-17 drugs would be the most cost-effective strategy at a willingness-to-pay threshold of \$150,000 per QALY.¹⁵ Wu et al. found that the annual costs per responder, for each of PASI 75, 90, and 100, were lowest for the IL-17 inhibitors compared with both adalimumab and ustekinumab.^{10,16} Supporting these findings is a recently updated consensus statement published in 2022 by the Psoriasis Group of the Spanish Academy of Dermatology and Venereology, which favoured IL-17 and IL-23 inhibitors for patients who are candidates for biologic therapy with considerations of the other drug classes (i.e., anti-TNF and anti-IL-12/23 biologics) in certain patients and clinical scenarios (e.g., presence of psoriatic arthritis or other comorbid conditions).¹⁸

Gross Expenditures of Old-Generation Biologics Beyond LoE

Biosimilar competition has not reduced expenditures to the degree that policy-makers had hoped for¹⁹; therefore, there may be a significant opportunity cost paid by society for originator biologics after LoE because the resources spent on these drugs could be reallocated to other health care priorities.²⁰ Exclusivity status, in this context, is defined as a function of patent and/or data protection. Patent protection is a 20-year period offered to innovative drugs from the date of filing that can be applied in various manners (e.g., chemical, change in use).⁸ Data protection regulations in Canada are governed by regulations under the Food and Drug Regulations published in 2006.^{21,22} These regulations provide data protection for an 8-year term with a possibility of adding 6 more months for submissions that include pediatric studies. During this time, only the owner or generator of preclinical and clinical trial data can use these data to obtain marketing authorization for drugs, effectively preventing a second-entry manufacturer from filing a submission for a copy of that innovative drug. Data protection begins from the time of issuance of Health Canada NOC and when the drug is added to Health Canada's Register of Innovative Drugs.^{21,22} Data protection for biologics in the US is longer than it is in Canada — it is 12 years from approval in the US.²³ Delays in biosimilar launch, which can span multiple years, are likely the result of, but not limited to, agreements between the originator and biosimilar manufacturers.^{24,25} Additionally, because the US market presents the largest opportunity for biosimilar developers,²⁶ global development of timelines for biosimilars may be based around US exclusivity timelines, which may also explain the delays that occur for biosimilar launches in Canada.

Canada is not the only market to experience delays in marketing of biosimilars.²⁷⁻²⁹ Prior investigations have demonstrated the financial impact biologics have had on health care systems. In an analysis of Australian Medicare expenditure data from 2015 to 2016 for biologics, the authors estimated that AU\$367 million would have been saved if biosimilars were available and listed, and if reduced monopoly protection length was advocated because this would save payers hundreds of millions of dollars per year.²⁰ A study conducted in Slovakia found that €35 million to €50 million per year could have been saved if biosimilars with marketing authorizations had been on the market.²⁸ Dickson et al. performed an analysis on US Medicare spending in which they estimated what the cost savings would have been

between 2015 and 2019 if biologics and biosimilars were subjected to the same Medicare reimbursement framework as brand name and generic drugs, which was found to be US\$1.6 billion.³⁰ Lee et al. calculated the cost of the delayed entry of the adalimumab biosimilars in the US between 2016 and 2019 (the biosimilars could not be marketed due to patent dispute settlements) and found that US\$2.2 billion would have been saved with timely biosimilar availability.²⁷ These studies demonstrate the substantial costs associated with originator biologics and how policy decisions (e.g., biosimilar substitution) can save health care dollars that could be used to fund other drugs and improve patient access to treatment. As such, finite expenditures on old-generation biologics also hinders the reimbursement of new-generation biologics, which have demonstrated favourable patient outcomes.⁹

Policy Issue

A patient's access to biologics for the treatment of PsO is dependent on meeting drug plan eligibility and coverage criteria, which varies across FPT drug plans. Additionally, before the advent of the pCPA, there was no formal process by which FPTs would discuss harmonized coverage criteria when listing new drugs on public formularies. The reimbursement of the originator versions of the old-generation biologics mostly predated pCPA, thus increasing the likelihood of fewer PLAs with public payers for these medications. The prevalence of PsO in Canada is increasing; therefore, the utilization of and spending on PsO biologics will also continue to rise. As the treatment paradigm changes over time considering the availability of new therapies and evidence, so can coverage criteria and policy decisions.

Evidence has emerged that demonstrates the new-generation biologics have greater efficacy and acceptable cost-effectiveness compared with old-generation biologics in PsO. Given this new evidence, the fact that the old-generation molecules have lost their exclusivity, and under the presumption that the new-generation biologics are appropriately priced for public payers given pCPA involvement, there is rationale for FPT drug plans to evaluate the utilization patterns of and expenditures on these therapies within their drug plans. Additionally, because exclusivity of biologics applies to all payers, this should be considered a national issue and expenditures post-LoE applies to private insurance as well.

Policy Questions

1. What is the market share of old- versus new-generation biologics for PsO in Canada within public drugs and across both public and private drug plans?
2. What is the cost of utilization of biologics for PsO within public drug plans?
3. What has been the opportunity cost in gross expenditures of old-generation originator biologics indicated for PsO after LoE in Canada?

Methods

Biologics for Plaque Psoriasis

PsO biologic drugs include originator biologics and biosimilars used to treat PsO in Canada (Table 1). Old-generation biologics include adalimumab, certolizumab pegol, etanercept, infliximab, and ustekinumab. New-generation biologics include brodalumab, guselkumab, ixekizumab, risankizumab, secukinumab, and tildrakizumab. All 5 of the old-generation biologics have had their data protection status expire or have predated the enactment of the data protection regulations of 2006 (Figure 1). Biosimilars are approved for adalimumab, infliximab, and etanercept despite registered patents for originators of both adalimumab and etanercept. The approval of these biologics predated data protection regulations thus data protection does not apply, although it has been more than 8 years since their respective NOC dates for PsO indications. The LoE dates provided in Table 1 were based on data protection expiry or launch of the originator’s biosimilar. Additional details can be found in a previously published CADTH report (Biologics in Plaque Psoriasis).

Public Drug Plans

Data Source

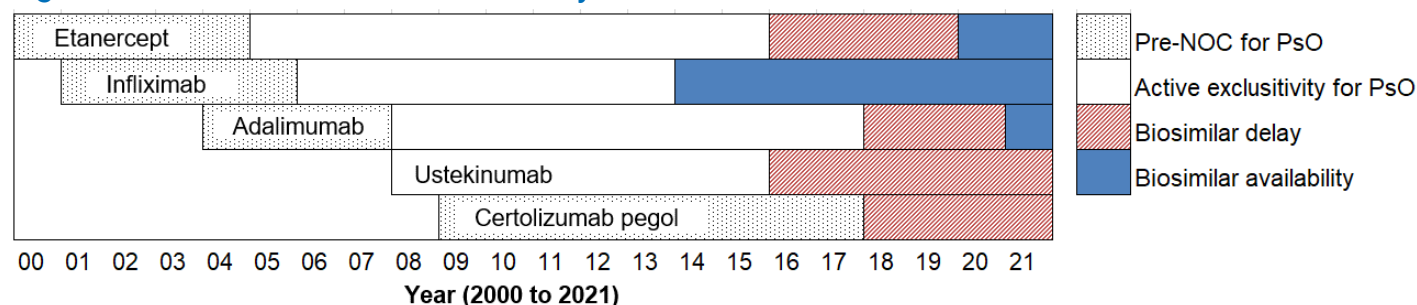
Claims data related to biologics indicated for PsO were extracted from the NPDUIS database for all public drug plans (except Quebec) and Yukon (Appendix 1) between January 1, 2014, and December 31, 2020, with an additional period used as a lead-in from January 1, 2000 (or earliest available data) to December 31, 2013, to examine existing and previous drug use. Only accepted drug claims, in which at least part of the claim was accepted by the public plan, either toward a deductible (if applicable) or for payment were included.

Approach

Because biologics are used to treat numerous indications, drug-marker algorithms based on existing and previous drug use were applied to identify patients receiving treatment for PsO (Appendix 2). Three different drug-marker algorithms were identified, developed in collaboration with a dermatologist with experience in treating patients with PsO, and each PsO cohort was analyzed separately.

The algorithms were developed recognizing that most patients with PsO are prescribed topical therapy at the time of diagnosis and may continue topical therapy throughout the course of their treatment. Access to PsO biologic drugs through public and private insurance

Figure 1: Time to Biosimilar Market Entry in Canada



NOC = Notice of Compliance.

Table 1: Regulatory Information for Biologics in PsO

Generic name	Brand name	Manufacturer	First NOC date	NOC date for PsO (if different from first NOC date)	Marketed date	Estimated annual cost ^a		Originator LoE date (if post-LoE)
						First year (induction)	Subsequent years (maintenance)	
Adalimumab	Humira	AbbVie Corporation	September 24, 2004	January 23, 2008	September 24, 2004	\$21,993	\$20,422	May 8, 2018
	Amgevita (biosimilar)	Amgen Canada Inc.	November 4, 2020	NA	February 19, 2021	\$13,196	\$12,253	NA
	Hadlima (biosimilar)	Samsung Bioepis Co., Ltd.	May 8, 2018	NA	February 19, 2021	\$13,196	\$12,253	NA
	Hulio (biosimilar)	BGP Pharma ULC	November 24, 2020	NA	February 16, 2021	\$13,196	\$12,253	NA
	Hyrimoz (biosimilar)	Sandoz Canada Inc.	November 4, 2020	NA	February 15, 2021	\$13,196	\$12,253	NA
	Idacio (biosimilar)	Fresenius Kabi Canada Ltd.	October 30, 2020	NA	February 16, 2021	\$13,196	\$12,253	NA
	Abrilada (biosimilar)	Pfizer Canada ULC	April 9, 2021	NA	Approved but not marketed ^b	NA		NA
Certolizumab pegol	Cimzia	UCB Canada Inc.	August 12, 2009	August 16, 2018	August 31, 2009	\$19,935- \$35,884	\$17,277- \$34,555	August 12, 2017
Etanercept	Enbrel	Amgen Canada Inc.	December 1, 2000	December 20, 2005	March 14, 2001	\$26,795	\$21,111	August 31, 2016
	Brenzys (biosimilar)	Samsung Bioepis Co., Ltd.	August 31, 2016	August 19, 2020	September 23, 2016	\$15,906	\$12,532	NA
	Erelzi (biosimilar)	Sandoz Canada Inc.	April 6, 2017	June 9, 2020	August 4, 2017	\$15,906	\$12,532	NA

Generic name	Brand name	Manufacturer	First NOC date	NOC date for PsO (if different from first NOC date)	Marketed date	Estimated annual cost ^a		Originator LoE date (if post-LoE)
						First year (induction)	Subsequent years (maintenance)	
Infliximab	Remicade[®]	Janssen Inc.	June 6, 2001	June 7, 2006	June 14, 2001	\$39,502	\$34,565	January 15, 2014; August 1, 2017
	Avsola (biosimilar)	Amgen Canada Inc.	March 12, 2020	NA	June 1, 2020	\$19,720	\$17,255	NA
	Inflectra (biosimilar)	Celltrion Health care Co., Ltd.	January 15, 2014	NA	September 4, 2014	\$21,000	\$18,375	NA
	Remsima (biosimilar)	Celltrion Health care Co., Ltd.	January 15, 2014	NA	Approved but not marketed ^b	NA		NA
	Renflexis (biosimilar)	Samsung Bioepis Co., Ltd.	December 1, 2017	NA	March 22, 2018	\$19,720	\$17,255	NA
Ustekinumab	Stelara	Janssen Inc.	December 12, 2008	NA	January 5, 2009	\$27,559	\$18,373	December 12, 2016
Guselkumab	Tremfya	Janssen Inc.	November 10, 2017	NA	November 27, 2017	\$24,478	\$18,358	NA
	Tremfya One- Press	Janssen Inc.	April 18, 2019	NA	May 20, 2019	\$24,478	\$18,358	NA
Risankizumab	Skyrizi	AbbVie Corporation	April 17, 2019	NA	May 13, 2019	\$29,610	\$19,740	NA
Tildrakizumab	Ilumya	Sun Pharma Global FZE	May 19, 2021	NA	August 4, 2021	\$29,610	\$19,740	NA
Brodalumab	Siliq	Bausch Health, Canada Inc.	March 6, 2018	NA	July 5, 2018	\$18,060	\$16,770	NA
Ixekizumab	Taltz	Eli Lilly Canada Inc.	May 25, 2016	April 1, 2021 (pediatric indication)	August 11, 2016	\$30,068	\$21,716	NA

Generic name	Brand name	Manufacturer	First NOC date	NOC date for PsO (if different from first NOC date)	Marketed date	Estimated annual cost ^a		Originator LoE date (if post-LoE)
						First year (induction)	Subsequent years (maintenance)	
Secukinumab	Cosentyx	Novartis Pharmaceuticals Canada Inc.	February 17, 2015	January 20, 2021 (pediatric indication)	April 10, 2015	\$28,560	\$21,840	NA

LoE = loss of exclusivity; NA = not applicable; NOC = Notice of Compliance; PsO = plaque psoriasis.

^aCalculated based on the recommended dose reported in the product monograph for PsO. Unit prices for all drugs except for guselkumab (not listed) were retrieved from the Ontario Drug Benefit (ODB) Formulary.³¹ For guselkumab, the unit price was retrieved from the IQVIA DeltaPA database.³²

^b“Approved but not marketed” refers to an active Drug Identification number (DIN) for a product that has been reviewed and authorized for sale in Canada but has not yet been marketed in Canada. “Marketed” refers to an active DIN for a product that is currently being sold in Canada.³³

^cOmyvence (infliximab, Janssen Inc.) was approved on December 29, 2020, by Health Canada. This product is not a biosimilar. The NOC submission was made for an “Additional Product Name” for Remicade. The product is approved by Health Canada but not yet marketed in Canada.^{34,35} The longest patent that was filed for the originator infliximab was found to be infringed by the biosimilar launch. The patent end date (August 1, 2017) was used in the base-case analysis for LoE, and a supplemental analysis was conducted using the January 15, 2014, date.

plans generally requires prior use of methotrexate and/or cyclosporine and may include prior use of apremilast and/or acitretin. Of these 4 drugs, methotrexate is the most frequently prescribed in PsO; however, it is also commonly prescribed before, and in conjunction with, PsO biologics used to treat other indications. Cyclosporine, apremilast, and acitretin are unlikely to be prescribed for non-PsO patients.

Regarding the 3 algorithms described in [Appendix 2](#), topical medications for Sensitivity Analysis Cohort 1 are not specific to PsO and could be prescribed for a number of dermatoses other than PsO; therefore, this cohort is thought to represent a maximum estimate of the number of patients treated with biologics for PsO. Topical drug markers for the primary cohort (i.e., base case) are specific to PsO and are expected to more accurately identify patients with PsO in Canada. Sensitivity Analysis Cohort 2 specifies prior use of cyclosporine or acitretin but not methotrexate. This cohort may represent a minimum estimate of the number of patients treated with biologics for PsO.

The following datasets were extracted from NPDUIS for each drug-marker algorithm:

- Number of active beneficiaries of PsO biologic drugs through public drug programs between 2018 and 2020. Claims were included from active beneficiaries who met the criteria defined in [Appendix 2](#).
- Number of new PsO biologic drugs through public drug programs between 2018 and 2020. A new PsO biologic user is defined as an individual who had at least 1 PsO biologic drug claim during the study period and had no previous claims for any PsO biologic drug in NPDUIS (starting 1 year after data were available).
- Number of new and total post-exclusivity PsO biologic drugs through public drug programs between 2014 and 2020. A new post-exclusivity PsO biologic user is defined as a new PsO biologic user whose first drug claim was after the data exclusivity date for that specific biologic ([Table 1](#)). LoE dates were based on the originator drug's data protection expiry date or its biosimilar launch date.

The number of claimants, claims, and costs (drug cost accepted, total prescription cost accepted, and total program paid) were collected and stratified by calendar year, jurisdiction, chemical, and type of biologic. Note the cost data do not reflect negotiated prices or discounts (i.e., PLAs) between the drug plan and the manufacturer.

Cell suppression was in accordance with CIHI privacy policy, where values with less than 5 beneficiaries (but greater than 0) were suppressed within a category. To minimize the impact of cell suppression, Atlantic public drug plans were pooled, and Yukon was excluded from the calculations. The Atlantic public drug plans include those of New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador.

Private Drug Plans

Data Source

Claims data related to the use of biologics for patients with PsO were extracted from Reformulary Group's prescription drug claims database for private drug plans. This database contains prescription drug claims paid by the provincial public drug plans as well as private employer-sponsored drug plans in Canada. Private plan claims data are sourced from medium to large insurers and represent approximately 5 million covered lives across the country. The earliest available data start July 1, 2013. Note that claims data from Nova Scotia are only available until June 2017 and that this database contains approximately

25% of all private drug plan claims in Canada. Because the data from Reformulary Group represents a small proportion of the private payer data, the data were only used to calculate utilization (i.e., market share). In addition, total expenditures since originator LoE related to all claims submitted to private insurers across Canada were provided by the CLHIA, which is an organization that represents 99% of Canada's life and health insurance companies. The final dataset provided by CLHIA and used in the current analysis represented 53% of all privately insured lives.

Approach

The private plan claims data were extracted from Reformulary Group's prescription drug claims database following the same methodology outlined for public drug plans, except claimants were individuals who submitted claims to private drug plans in Canada whose claims were not rejected or denied. However, in determining PsO indication, not all users had their claims history available (e.g., new plans added to the database over time or new to plan members). In these cases, applying a drug-marker algorithm based on previous drug use was not feasible and available user indication data and Reformulary Group's proprietary inferred diagnosis algorithms were applied to determine use diagnosis. Additionally, carrier indication information was available for some insurers, and this was used to determine PsO indication in these cases. Patients may also switch between different private drug plans, which could lead to the false identification of new biologic users. To limit this possibility, claimants with less than 4 months of claims history were not considered new biologic users because none of the biologics indicated for PsO have a regimen that is less frequent than once every 4 months. Private claims data were analyzed for the base-case population.

From the CLHIA data, the total costs of submitted claims, by chemical and year (between 2016 and 2020), were provided and used to calculate expenditures post-LoE across private drug plans in Canada. Similar to the data on public drug plans, the cost data provided by private payers also do not reflect PLAs between the drug plan and manufacturer. The data were provided direct from the carriers and collated and blinded by CLHIA. Of note, 2 providers did not submit the requested data and 1 other provider's dataset began after June 2016.

Data Analysis

A brief description of each of the analyses conducted for this report follows. Additional details on the study design and analytical methods are available in [Appendix 3](#). Utilization patterns and cost of utilization per claimant for each drug were analyzed within the public drug plan data. The utilization data of both the public and private drug plan data were combined nationally. The base case for each analysis was conducted using the data for the primary cohort, and sensitivity analyses based on the different drug-marker algorithms were performed using the data for Sensitivity Analysis Cohorts 1 and 2 ([Appendix 2](#)).

Utilization Patterns

The utilization patterns of old- and new-generation biologics for PsO were analyzed by calculating the market share of each drug (as a proportion of all claimants who made a claim for a given drug) from 2018 to 2020. This calculation was performed within jurisdictions and at the national level. To combine the utilization data of public and private drug plans, the number of claimants within the Reformulary Group private claims dataset was multiplied by 4 because this dataset represented approximately 25% of all private drug plan claims in Canada.

Cost of Utilization per Claimant

The average cost of utilization (total prescription cost accepted) per claimant nationally in 2020 was also calculated for each drug and by type of biologic (i.e., originator versus biosimilar) across public drug plans.

Gross Expenditures of Old-Generation Biologics Beyond LoE

Gross expenditures for each old-generation originator biologic were estimated by calculating the costs that have accumulated since the date each drug lost its exclusivity status. The gross expenditures for each old-generation originator biologic were summed to estimate the total expenditures on these drugs since LoE, and the results obtained for both the public and private drug plan data were summed, when feasible, to estimate how much has been spent since originator LoE across Canada. Because the data provided by CLHIA were used to calculate total expenditures since LoE among private drug plans and represented 53% of privately insured lives, the gross expenditure estimates for each drug resulting from this data were extrapolated accordingly. Analyses were performed for both new claimants only (i.e., first claim for a biologic) and all claimants (i.e., new and returning biologic drug claimants). A supplemental analysis was also conducted based on the 2 LoE dates identified for the originator infliximab.

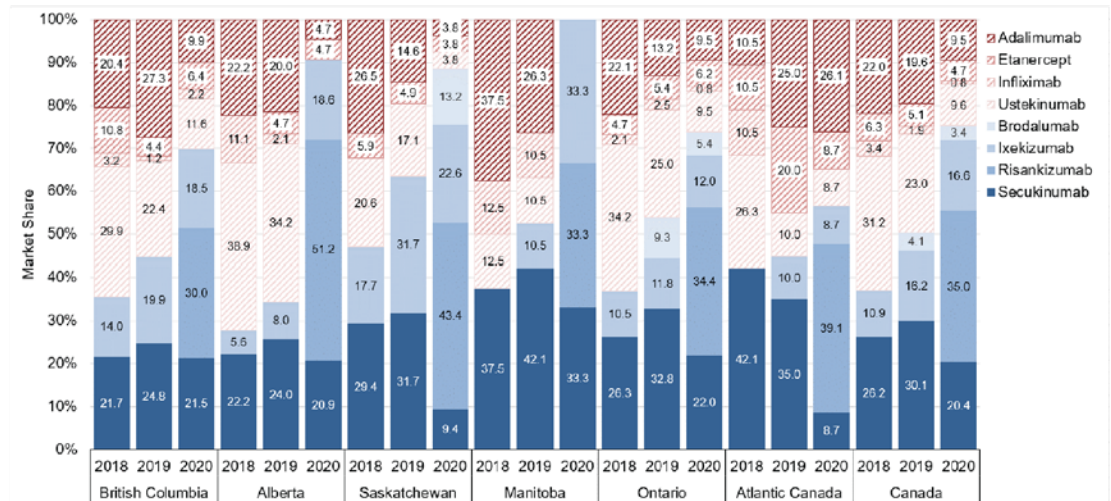
Findings

Utilization Patterns of Old- Versus New-Generation Biologics in PsO Across Public Drug Plans

Across public drug plans, claims for old-generation biologics included adalimumab, etanercept, infliximab, and ustekinumab, and claims for new-generation biologics included brodalumab, ixekizumab, risankizumab, and secukinumab. There were 1,521 new claimants with PsO among the public claims between 2018 and 2020. In this group, there was a year-to-year increase in the use of new-generation biologics nationally across Canada and within each jurisdiction from 2018 to 2020; by 2020, the new-generation drugs were prescribed more often than the old-generation molecules ([Figure 2](#)). The proportion of new claimants with PsO using new-generation biologics in 2020 was approximately 75% nationally, which ranged from 56.5% (Atlantic Canada) to 100% (Manitoba) across jurisdictions. Manitoba, Alberta, and Saskatchewan had the greatest proportions of new claimants who received a new-generation biologic in 2020, at 100%, 90.7%, and 88.7%, respectively. Among claims for new-generation biologics in 2020, risankizumab (35.0%) had the greatest market share, followed by secukinumab (20.4%), ixekizumab (16.6%), and then brodalumab (3.4%). Among claims for old-generation biologics in 2020, ustekinumab (9.6%) had the greatest market share, followed by adalimumab (9.5%), etanercept (4.7%), and then infliximab (0.8%). Of note, most claims for etanercept and infliximab were for their biosimilars. Additionally, the national cost of utilization per claimant estimate was greatest with originator ustekinumab (\$16,047) among new claimants with PsO in 2020 ([Figure 3](#)). Originators secukinumab (\$15,229) and etanercept (\$14,862) were second and third, respectively, followed by originators ixekizumab (\$14,640), risankizumab (\$13,957), adalimumab (\$11,645), and brodalumab (\$8,303). Of note, there were no claims for originator infliximab among new claimants with PsO in 2020. Overall, the average cost of utilization per claimant for new-generation biologics

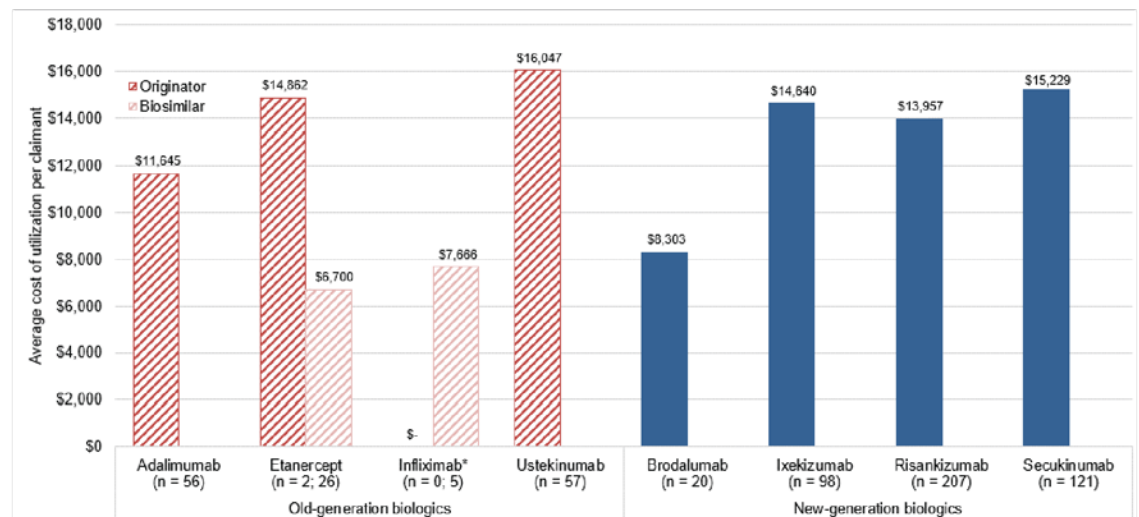
among new claimants with PsO was found to be lower than or similar to the old-generation originator molecules.

Figure 2: Market Share of Old- Versus New-Generation Biologics Among New Claimants With PsO Across Public Drug Plans in Canada by Jurisdiction (2018 to 2020)



Note: Blue/solid bars = new-generation biologics; red/stripped bars = old-generation biologics.

Figure 3: National Average Annual Cost of Utilization per Claimant for PsO Biologics Among New Claimants with PsO Across Public Drug Plans in Canada (2020)



n = number of claimants; PsO = plaque psoriasis.

Note Blue/solid bars = new-generation biologics; red/stripped bars = old-generation biologics. Costs do not reflect product listing agreements between drug plans and manufacturers.

There were no claims for originator infliximab among new claimants with PsO in 2020.

The increased use of new-generation biologics is also evident when examining trends among all claimants (i.e., new and returning biologic drug claimants) with PsO (the market share of new-generation biologics went from 21.4% in 2018 to 42.7% in 2020) as presented in [Appendix 4](#). Among this group, old-generation originator biologics also exhibited the greatest cost of utilization per claimant in 2020.

Utilization patterns demonstrate that the use of new-generation biologics among patients with PsO has increased over time across FPT drug plans, although their use is more prevalent among new claimants. These patterns are consistent across all jurisdictions. Among new claimants with PsO in Canada, approximately 25% initiated treatment with an old-generation biologic in 2020, although this proportion was lower in Manitoba, Alberta, and Saskatchewan, indicating variation in prescribing patterns for new drug claimants with PsO across jurisdictions. Sensitivity analyses revealed the effect of drug-marker algorithm selection on this estimate, which ranged from 20.8% to 49.0% across the different scenarios ([Appendix 5](#)).

Utilization Patterns of Biologics for PsO Across Public and Private Drug Plans

Across both public and private drug plans, claims for old-generation biologics included the same drugs as public plans only, but also included certolizumab pegol, and claims for new-generation biologics also included the same drugs as public plans only, except guselkumab claims were made as well. Among private claims, new claimants with PsO represented 1,432 claimants (before extrapolating claims to estimate the total population of privately insured claims) between 2018 and 2020. After combining the data from public and private drug plans, the year-to-year increases in the use of new-generation biologics in Canada from 2018 to 2020 among new drug claimants with PsO were still present ([Figure 4](#)). For 2020, after combining the public and private drug plan data the proportion of new claimants with PsO who had a claim for a new-generation biologic was approximately 56% nationally. Among this combined dataset for 2020, for new-generation biologics, risankizumab had the greatest market share followed by secukinumab, guselkumab, ixekizumab, and then brodalumab. Among old-generation biologics within this combined dataset for 2020, adalimumab had the greatest market share followed by infliximab, ustekinumab, etanercept, and then certolizumab pegol.

Although there has been a year-to-year increase in the use of the new-generation biologics among new biologic drug claimants with PsO across both public and private drug plans in Canada, old-generation biologics are still being prescribed; approximately half (44%) of these patients were prescribed an old-generation biologic in 2020. However, these trends suggest that the use of new-generation biologics will likely increase in future years.

Gross Expenditures of Old-Generation Biologics Beyond LoE Among Public Drug Plans and Patients With PsO

Due to data limitations, estimating gross expenditures among the different claimant groups within the private payer data was not feasible. The estimated drug plan expenditures since originator LoE among the different claimant groups within the public payer data for the base-case analysis are provided in [Table 2](#), and the results of the supplemental analysis based on the 2014 LoE date for infliximab are provided in [Appendix 6](#).

For new claimants with PsO who initiated treatment between 2016 and 2020 with an old-generation originator biologic indicated for PsO, it is estimated that public drug plans spent

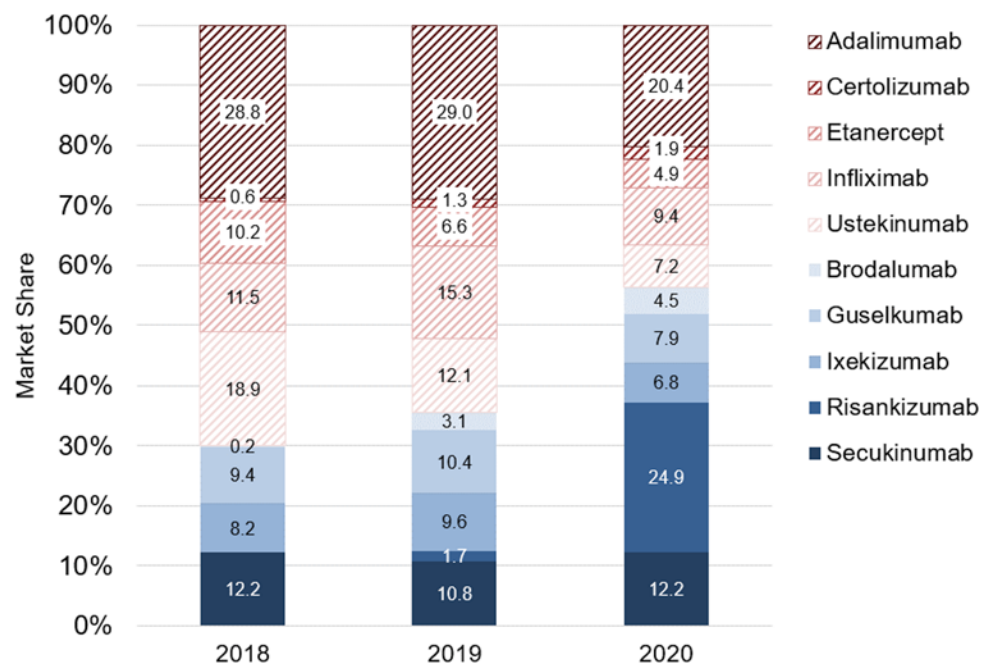
\$27.9 million nationally on their treatment since originator LoE, which represents 4.6% of the gross expenditures on these drugs among new claimants across all indications (\$600.4 million). Within this group, ustekinumab made up the greatest share of spending (71.4%), followed by etanercept (18.4%), adalimumab (9.2%), and infliximab (1.1%). Sensitivity analyses based on drug-marker algorithms demonstrated that the estimated gross expenditures among new drug claimants with PsO ranges from \$18.2 million to \$115.7 million.

Among all claimants with PsO, public drug plans have spent approximately \$124.1 million nationally on old-generation originator biologics since their LoE (Table 2), which represents 4.0% of the gross expenditures on these drugs among all claimants across all indications (\$3.1 billion). Ustekinumab made up the greatest share of this spending (49.0%), followed by adalimumab (25.2%), etanercept (20.4%), then infliximab (5.4%). Sensitivity analyses based on drug-marker algorithms demonstrated that the estimated gross expenditure among all claimants with PsO ranges from \$74.4 million to \$515.7 million. The wide range of estimates among claimants with PsO (compared with the total spending on originator biologics indicated for PsO since LoE) shows that the PsO indication itself represents a small proportion of the total expenditures on these drugs.

Gross Expenditures of Old-Generation Biologics Beyond LoE Among Public and Private Drug Plans

Before extrapolating the gross expenditure estimates from the private claims data (CLHIA data represented 53% of privately insured lives), it is estimated that, among all claims across

Figure 4: National Market Share of Old- Versus New-Generation Biologics Among New Claimants With PsO Across Public and Private Drug Plans in Canada (2018 to 2020)



Note: Blue/solid bars = new-generation biologics; red/striped bars = old-generation biologics.

all indications for an old-generation originator biologic between 2016 and 2020, public and private drug plans combined spent approximately \$6.2 billion since originator LoE. However, after extrapolation of the private claims data, this estimate increased to \$9.0 billion nationally (Figure 5). Originator infliximab made up the greatest share of this spending (39.3%), followed by adalimumab (28.8%), etanercept (14.9%), ustekinumab (14.6%), and certolizumab pegol (2.5%). In the analysis using the 2014 LoE date for infliximab, total spending on these drugs since originator LoE across all indications was estimated at \$11.8 billion (\$4.3 billion from public and \$7.5 billion from private plans) after extrapolation of the private claims data (this estimate was \$8.3 billion before extrapolation).

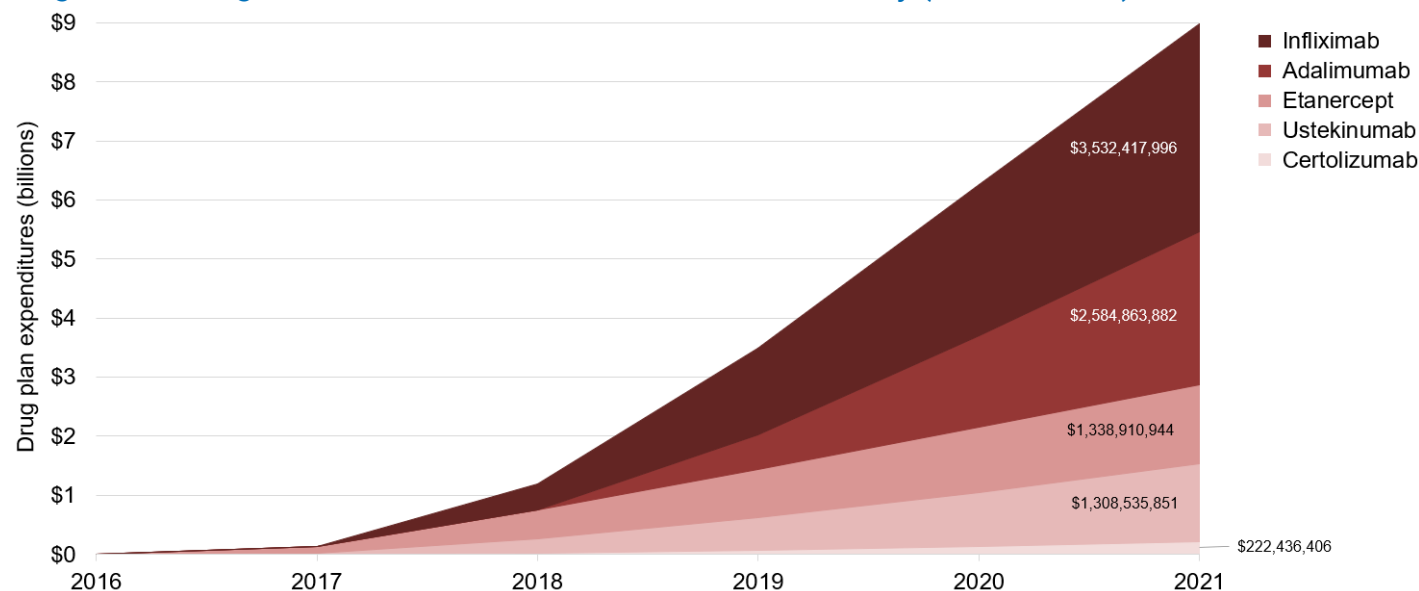
Table 2: Public Drug Plan Expenditures on All and New Claimants Since Loss of Exclusivity of Old-Generation Originator Biologics Indicated for PsO

Analysis	Claimants prescribed a biologic for any indication		Claimants with PsO indication only (based on drug-marker algorithm)			
	All claimants	New claimants	All claimants (base case)	All claimants (SA range)	New claimants (base case)	New claimants (SA range)
Base case (2016 to 2020)	\$3,125,232,178	\$600,379,615	\$124,094,048	\$74,416,111 to \$515,655,301	\$27,868,963	\$18,173,726 to \$115,738,461

PsO = plaque psoriasis; SA = sensitivity analysis.

Note: Costs do not reflect product listing agreements between drug plans and manufacturers.

Figure 5: Cumulative Public and Private Drug Plan Expenditures on All Claims for Old-Generation Originator Biologics Indicated for PsO Since Loss of Exclusivity (2016 to 2020)



PsO = plaque psoriasis.

Note: For each molecule, expenditures accumulated in the year when exclusivity was lost. Cost estimates for private claims were extrapolated because the data provided by CLHIA represented 53% of privately insured lives. Costs do not reflect PLAs between drug plans and manufacturers.

Study Limitations

The current analyses have a number of limitations that warrant highlighting:

- The claims data were not indication-specific, and a drug-marker algorithm was required to identify patients with PsO. Due to differences in coverage criteria across drug plans, 3 different drug-marker algorithms were developed, which introduces greater uncertainty (i.e., a wider range of outcomes) in the results. Additionally, because the biologics indicated for PsO can also be used to treat other conditions, and a drug-marker algorithm is dependent on having an accurate history of a patient's prior drug claims, it is also possible that data for patients without PsO were still included in the analyses. Drug-marker algorithms were applied that considered existing and previous drug use representative of patients receiving treatment for PsO. Three different drug-marker algorithms were developed that considered differences in reimbursement criteria across drug plans, and sensitivity analyses were conducted to demonstrate the range of possible outcomes around these results.
- The current analysis is on the utilization of biologics only and provides no information on the reasons behind these treatment decisions. Differences in drug plan PLAs, coverage criteria and access, patient input and preferences, patient comorbidities, and physician preferences also play a role in treatment decisions, and it is unclear to what degree each of these factors influences drug utilization. There is also no efficacy or safety data included in this analysis, so there is no patient outcome data.
- The cost per claimant estimates are a function of utilization, dosing, and price. It is unclear how long patients were on the same treatment in a given year (i.e., the patient may have stopped or switched treatment) or their dosing may not have been in accordance with the product monograph. Because many of the old-generation biologics predated pCPA, PLAs among drug plans are unknown and it is not possible to take into account the subsequent discounts included in PLAs, which adds more uncertainty when comparing the cost per claimant between drugs.
- Some of the claims data were suppressed; in these situations, assumptions were made on the number of claimants and their associated costs. However, there were few such cases, and it is expected that this had a limited impact on the results.
- The LoE dates of drugs marketed before the data protection regulations made in 2006 were assumed based on their NOC or launch of their biosimilar. If the current data protection regulations existed when the old-generation originator biologics were initially marketed, these drugs may have had different LoE dates, which would have yielded different gross expenditure estimates. It is also feasible that, for the biologics in which the end of data protection date was considered the LoE date, LoE may actually be beyond data protection and up to the patent loss date. However, the 2 drugs beyond data protection are also beyond patent loss.
- Patients being treated with a new-generation biologic may fail treatment over time; therefore, there is still a place in therapy for the old-generation molecules because they could be considered appropriate therapeutic options in this situation. It is unclear what proportion of the estimated gross expenditure post-LoE among all claimants represents such cases.
- The private payer market share and cost per claimant results were based on a proportion (approximately 25%) of all private claims. It is possible that the results would be different if all private payer data were available.

- Regarding the gross expenditure estimates, the private payer costs were based on submitted claims. Just 53% of privately insured lives were represented in the data provided by CLHIA, which were extrapolated to calculate the total expenditures since LoE among private drug plans, introducing some uncertainty in these expenditures particularly in the upper range estimate.
- There may be a substantial proportion of patients who transitioned between private and public coverage, which could have affected the results about new claimants because some could actually be existing patients changing between drug plans. Changes in claims made within catastrophic drug coverage programs in Canada demonstrate the potential for this dynamic, especially for claims made for high-cost biologics.³⁶ This is also a reason why both public and private drug plan data were considered in the current analysis. Patients may also switch between different private drug plans, which could lead to the false identification of new users, although a method was implemented to limit this possibility (i.e., because none of the biologics indicated for PsO have a regimen that is less frequent than once every 4 months, claimants with less than 4 months of claims history were not considered new biologic users).

Conclusions and Implications for Decision- or Policy-Making

Despite access to new-generation biologics with a favourable efficacy profile, a significant use of old-generation biologics in new patients with PsO persists within both public and private drug plans. Jurisdictions with a biologic tiering policy (i.e., Manitoba and Alberta) have the most prevalent use of new-generation drugs, which suggests a change in reimbursement criteria by payers may promote the use of new-generation biologics. The annual cost per patient (excluding PLAs) typically tends to be higher for old-generation originator biologics and, despite LoE, some of these drugs do not currently have a biosimilar version available (i.e., ustekinumab and certolizumab pegol). This cost difference may be even greater among public drug plans if net prices were assessed given that the new-generation biologics underwent pCPA negotiations.

It is unclear why physicians are prescribing old-generation biologics for new PsO biologic starts given their difference in efficacy compared to the new drugs. Various factors could play a role in this decision, such as comfort with the old-generation biologics, patient preference, or marketing efforts by pharmaceutical companies.³⁷⁻³⁹ Payers should consider assessing their place in therapy or improving their value as biologic dose escalation, which comes with increased costs, is also present in Canada; the use of new, more efficacious, and appropriately priced therapies should help alleviate this burden.⁴⁰ Global agreements and a shorter data protection period in Canada may be driving this expenditure post-LoE. Physician prescribing patterns may reflect that there are no recent Canadian treatment guidelines on the management of patients with PsO.

Payers should consider assessing how to get better value from these drugs given the scale of the spend. Canada has spent up to \$9.0 billion on originator biologics indicated for PsO post-LoE from 2016 to 2020. To put this in perspective, spending on oncology drugs in Canada in the latest reported year (2019) was \$3.9 billion and spending on the top 50 drugs in the 2019–2020 fiscal year was \$4.3 billion (according to recent reports based on data

from the NPDUIS).⁴¹⁻⁴³ Therefore, given the significant expenditures on these 5 old-generation originator biologics indicated for PsO, more focus should be applied to addressing formulary management in this area. Additional research in this area should also help clarify the uncertainty around these estimates.

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Appendix 1: Public Drug Plans and Programs Within the NPDUIS Database

Note that this appendix has not been copy-edited.

Table 3: List of Provincial Public Drug Plans and Programs in the NPDUIS Database During the Requested Time Period (January 1, 2014, to December 31, 2020)

Jurisdiction	Plan/program description
Alberta	Non-Group Seniors Palliative Care
British Columbia	Fair Pharma Care Permanent Residents of Licensed Residential Care Facilities Recipients of British Columbia Income Assistance Cystic Fibrosis Children in the At Home Program No-Charge Psychiatric Medication Program BC Palliative Care Drug Plan Smoking Cessation
Manitoba	Employment and Income Assistance Program Palliative Care Pharmacare Personal Home Care/Nursing Homes
New Brunswick	New Brunswick Prescription Drug Program, including: <ul style="list-style-type: none"> • Seniors • Nursing Home Residents • Social Development Clients • Individuals in Licensed Residential Facilities • Children in Care of the Minister Social and Special Needs Children • Multiple Sclerosis • Tuberculosis • Pharmacist Administered Vaccines • HIV/AIDS • Cystic Fibrosis • Organ Transplant Recipients • Growth Hormone Deficiency New Brunswick Drug Plan Medical Abortion Plan

Jurisdiction	Plan/program description
Newfoundland and Labrador	The Foundation Plan The 65Plus Plan The Access Plan Select Needs/Cystic Fibrosis Plan Select Needs/Growth Hormone Plan Assurance Plan Child Youth and Family Services Long-Term Care Personal Care Home Provincial/Pandemic Plan Home Support Services
Nova Scotia	Diabetic Assistance Program Palliative Drug Care Program Pharmacare Long-Term Care (Under 65) Drug Assistance for Cancer Patients Seniors' Pharmacare Program Family Pharmacare Program
Ontario	Ontario Drug Benefit Program (ODB)
Prince Edward Island	Diabetes Control Program Generic Drug Program Opioid Replacement Therapy Drug Program Immunization Program Family Health Benefit Program High-Cost Drug Program Nursing Home Seniors' Drug Cost Assistance Program Catastrophic Drug Program Children in Care Financial Assistance Sexually Transmitted Diseases Smoking Cessation Program
Saskatchewan	Universal Program
Yukon	Chronic Disease Program Children's Drug and Optical Plan Pharmacare

NPDUIS = National Prescription Drug Utilization Information System.

Appendix 2: Drug-Marker Algorithms for PsO

Note that this appendix has not been copy-edited.

Three different PsO cohorts were identified based on the criteria outlined below.

Base case

- At least 1 claim for a PsO biologic drug was identified within the study period.
- At least 1 claim for cyclosporine, acitretin, or methotrexate, but no PsO biologic drug claim, in the 365 days before the index claim*. If the individual only had claims for methotrexate, check for at least 1 other PsO drug-marker ([Table 4](#)) claim in the 730 days (when available) before their index claim.

Table 4: Drug Markers for the Primary Cohort

Type	Drug
Vitamin D analogues	Calcipotriene (or calcipotriol) Calcitriol Tacalcitol
Coal tar	Coal tar lotion Coal tar extract
Other	Tazarotene Anthralin (dithranol)
Combination therapies	Betamethasone/calcipotriol

Sensitivity Analysis 1

- At least 1 claim for a PsO biologic drug was identified within the study period.
- At least 1 claim for a PsO drug marker ([Table 5](#)), but no PsO biologic drug claim, in the 365 days before the index claim*. If the individual only had claims for methotrexate, check for at least 1 other PsO drug-marker claim in the 730 days (when available) before their index claim.

Table 5: Drug Markers for the Sensitivity Analysis Cohort 1

Type	Drug
Topical steroids	Betamethasone dipropionate Clobetasol propionate Desoximetasone Diflorasone diacetate Fluocinonide Flurandrenolide Halobetasol propionate Amcinonide Halcinonide Mometasone furoate Triamcinolone acetonide Betamethasone valerate Fluticasone propionate Hydrocortisone valerate Clocortolone pivalate Fluocinolone acetonide Flurandrenolide Hydrocortisone butyrate Hydrocortisone probutate Prednicarbate Alclometasone dipropionate Desonide Dexamethasone sodium phosphate Methylprednisolone acetate
Calcineurin inhibitors	Tacrolimus Pimecrolimus
Vitamin D analogues	Calcipotriene (or calcipotriol) Calcitriol Tacalcitol
Moisturizers	Emollients
Coal tar	Coal tar lotion Coal tar extract
Other	Tazarotene Anthralin (dithranol) Apremilast

Appendix 3: Study Design and Analytical Methods

Note that this appendix has not been copy-edited.

Study Design

Utilization Patterns and Cost of Old- and New-Generation Biologics in PsO

To determine the utilization patterns of old- and new-generation biologics, the number of claimants for each biologic was counted for each drug plan to calculate the proportion of utilization of the different biologics (by chemical and calendar year between 2018 and 2020). Analyses were conducted within each jurisdiction, when feasible (limited by cell suppression within the public drug plan data), and at the national level for all (i.e., new and returning biologic drug claimants) and new claimants (i.e., new biologic drug claimants only) for each calendar year.

Additionally, to compare costs between old- and new-generation biologics for PsO, the national cost (total prescription cost accepted) per claimant was calculated (by chemical and type of biologic [i.e., originator or biosimilar]) for all and new claimants.

Combining Utilization Data of Public and Private Drug Plans

To combine the utilization data of public and private drug plans, the analyses described above were conducted after adding the number of claimants within public drug plans with the number of claimants within private drug plans; however, as the private claims data obtained from the Reformulary Group were used in this analysis, the number of claimants within this dataset were multiplied by 4 as it represented approximately 25% of all private drug plan claims in Canada.

Gross Expenditures of Old-Generation Biologics Beyond LoE

The gross expenditure of old-generation originator biologics after LoE were estimated using the total prescription cost accepted data. The claims data from CLHIA were used in the calculations related to the private payer data. Total expenditures were estimated among all claimants prescribed an originator biologic indicated for PsO (i.e., new and returning biologic drug claimants regardless of the actual indication being treated), new claimants prescribed an originator biologic indicated for PsO (i.e., new biologic drug claimants only and regardless of the actual indication being treated), and among all (i.e., new and returning biologic drug claimants with PsO) and new claimants with PsO (i.e., new biologic drug claimants only with PsO) according to the drug-marker algorithm. Costs were calculated (by chemical and calendar year) within each jurisdiction, when feasible (limited by cell suppression within the public drug plan data), and at the national level. To calculate expenditures after originator LoE among new claimants, an annual withdrawal rate of 6.5% was used as an estimate of the proportion of claimants who discontinue treatment each year.⁴⁴ Of note, 2 LoE dates were identified for the originator infliximab due to patent infringement by the biosimilar launch and a supplemental analysis was conducted based on these different dates. The gross expenditure among public and among private plans were summed, when feasible, to estimate total drug spending in Canada on these biologics since LoE.

Analytical Methods

In cases where public claims data for a given chemical was suppressed in accordance with CIHI privacy policy (values with less than 5 beneficiaries, but greater than 0, were suppressed), it was assumed that 2 claimants made a claim for the drug and the national cost per claimant estimate (according to the type of biologic and the calendar year of the suppressed claims data) was used to calculate the total prescription cost accepted of the suppressed values.

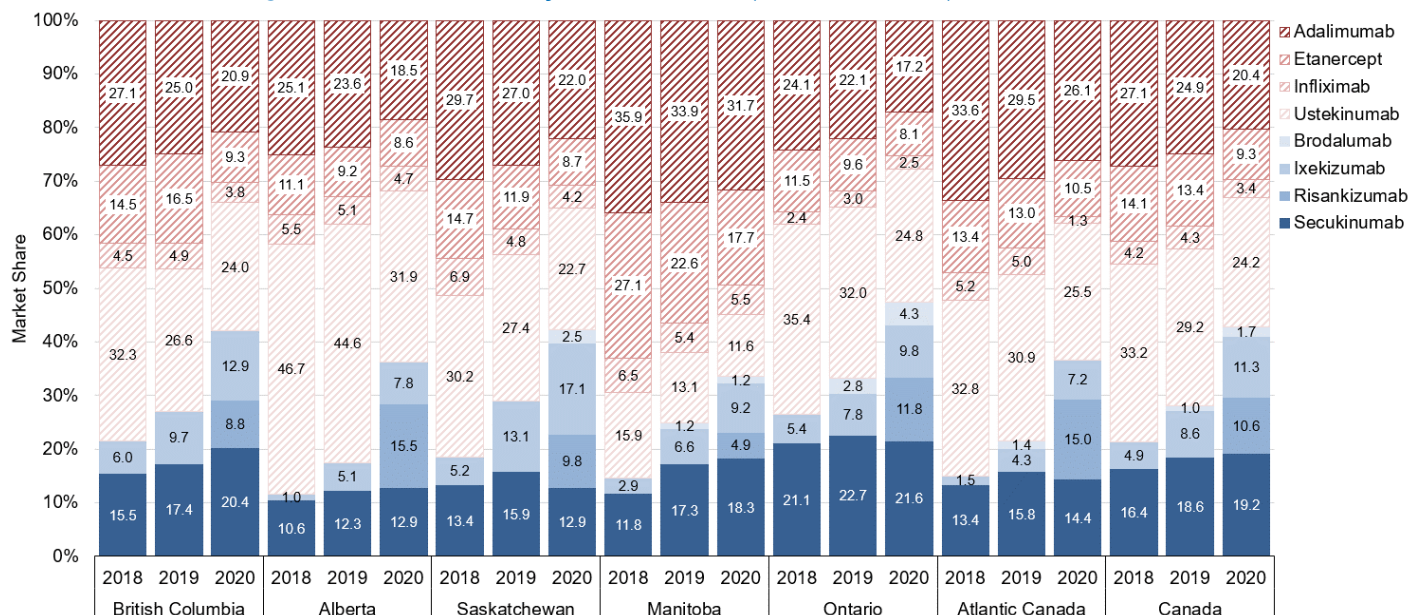
No statistical analyses were planned for this study. There were also no minimal clinically important difference thresholds to consider for this study. The analyses performed for this study were conducted to assess trends and numerical differences in the utilization of biologic drugs for PsO and total expenditures since their LoE across Canada, considering both public and private drug plans. As the data provided by CLHIA were used to calculate total expenditures since LoE among private drug plans and represented 53% of privately insured lives, the gross expenditure estimates for each drug resulting from this data were extrapolated accordingly.

The primary cohort represented the base-case analysis, and sensitivity analyses were conducted to examine the impact of the different drug-marker algorithms on the results of the base-case analysis (refer to the drug-marker algorithms outlined in [Appendix 2](#) for a description of each cohort). Additionally, as 2 LoE dates were identified for the originator infliximab, a supplemental analysis was also conducted to examine the differences in expenditures since LoE between these 2 dates, with the latest date, August 1, 2017, used in the base-case analysis and the earliest date, January 15, 2014, used in the supplemental analysis.

Appendix 4: Additional Utilization Results of Biologic Use Among Claimants With PsO Across Public Drug Plans in Canada

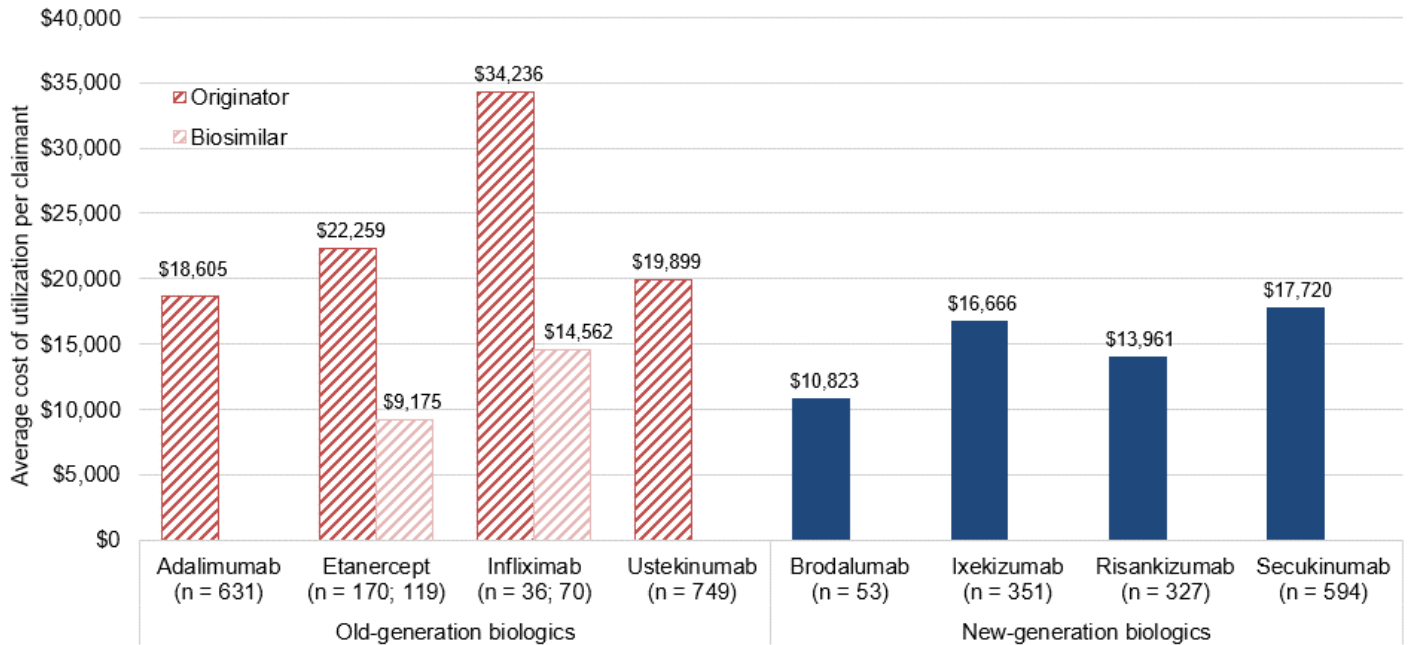
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Figure 7: Market Share of Old- Versus New-Generation Biologics Among All Claimants With PsO Across Public Drug Plans in Canada by Jurisdiction (2018 to 2020)



Note: Blue/solid bars = new-generation biologics; red/striped bars = old-generation biologics.

Figure 8: Average Cost of Utilization per Claimant for PsO Biologics Among All Claimants With PsO Across Public Drug Plans in Canada (2020)



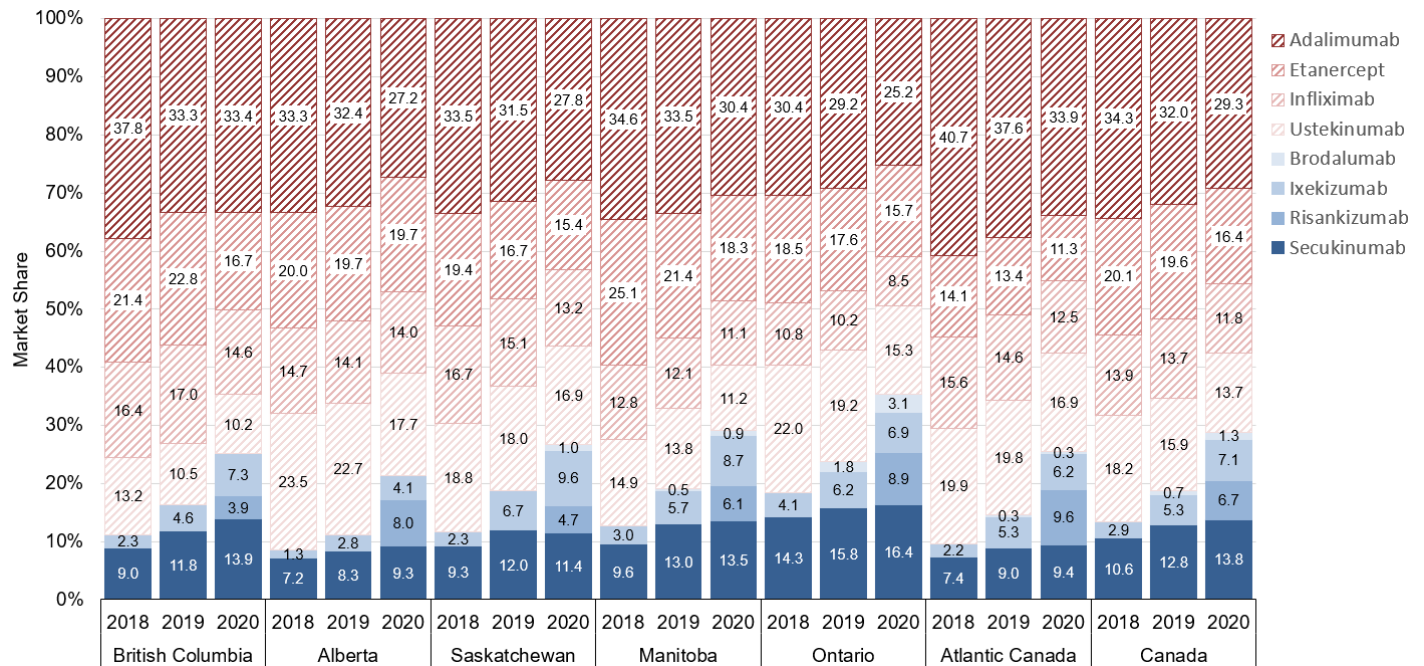
n = number of claimants; PsO = plaque psoriasis.

Note: Blue/solid bars = new-generation biologics; red/striped bars = old-generation biologics.

Appendix 5: Sensitivity Analysis Results on the Utilization of Old- Versus New-Generation Biologics for PsO Across Public Drug Plans in Canada

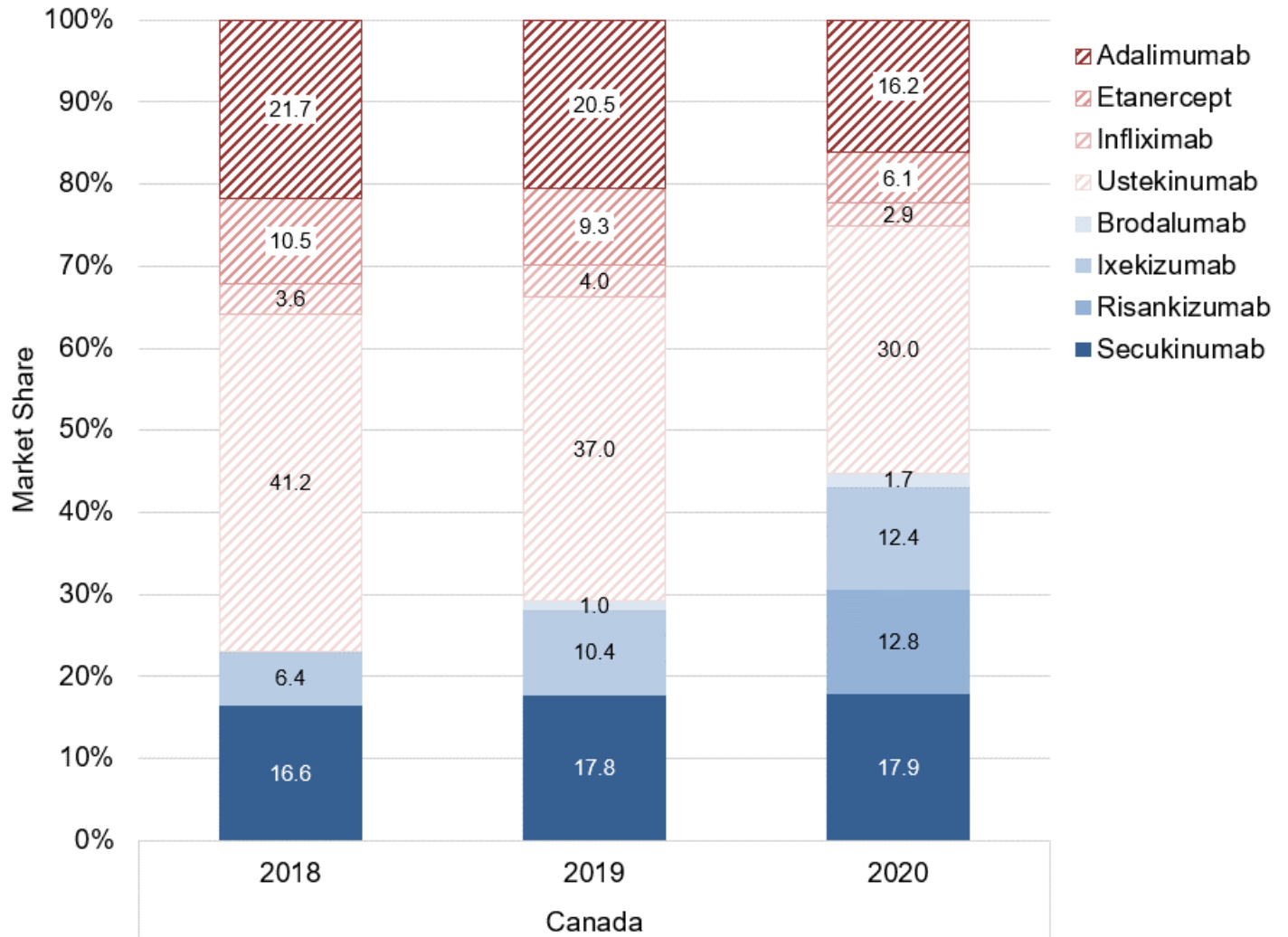
Note that this appendix has not been copy-edited.

Figure 9: Market Share of Old- Versus New-Generation Biologics Among All Claimants With PsO Across Public Drug Plans in Canada by Jurisdiction (2018 to 2020) – Sensitivity Analysis 1



Note: Blue/solid bars = new-generation biologics; Red/striped bars = old-generation biologics.

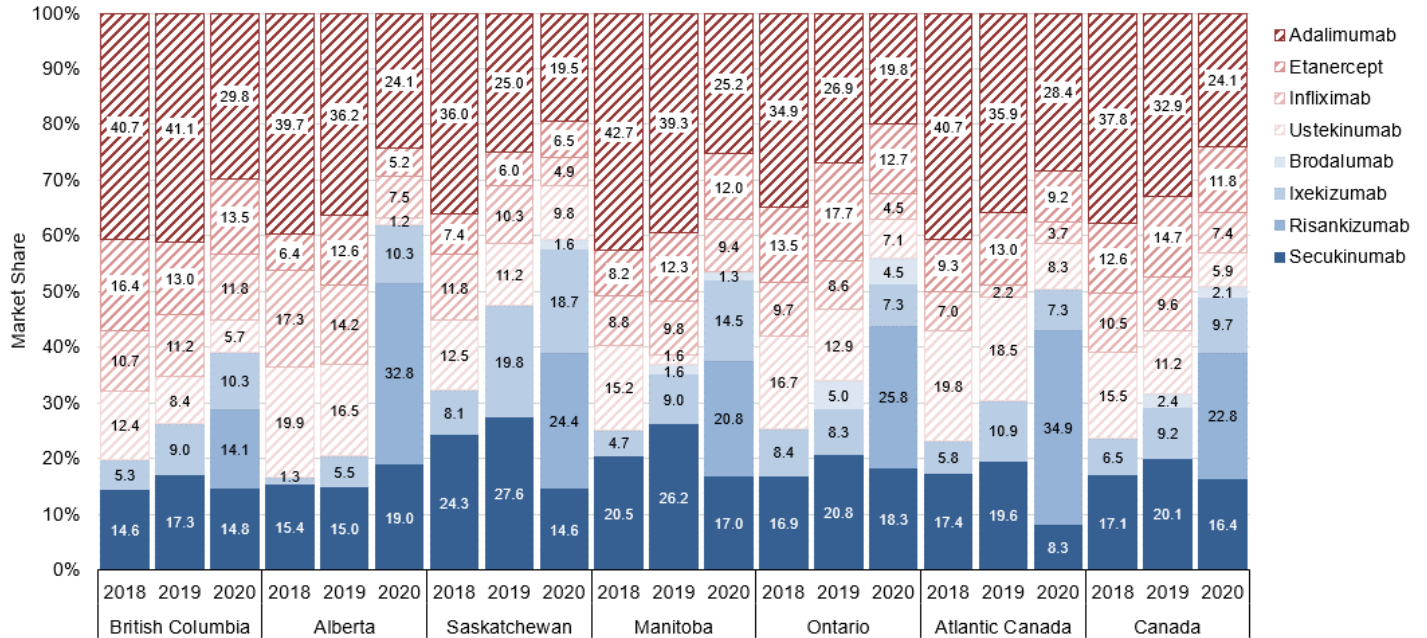
Figure 10: Market Share of Old- Versus New-Generation Biologics Among All Claimants With PsO Across Public Drug Plans in Canada (2018 to 2020) – Sensitivity Analysis 2



PsO = plaque psoriasis.

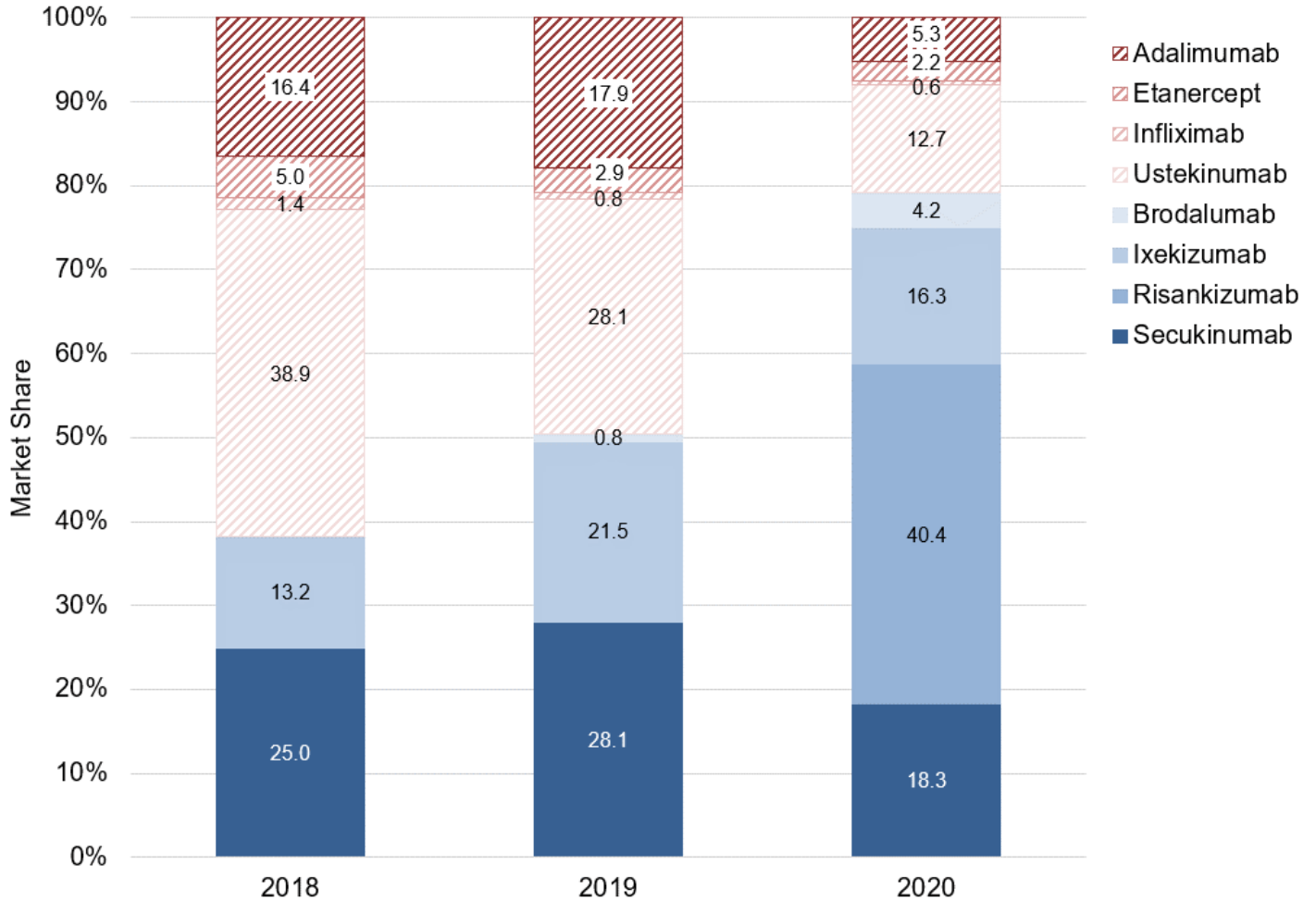
Note: Blue/solid bars = new-generation biologics; red/striped bars = old-generation biologics. Results by jurisdiction were not feasible due to suppressed data.

Figure 11: Market Share of Old- Versus New-Generation Biologics Among New Claimants With PsO Across Public Drug Plans in Canada by Jurisdiction (2018 to 2020) – Sensitivity Analysis 1



Blue/solid bars = new-generation biologics; Red/striped bars = old-generation biologics.

Figure 12: Market Share of Old- Versus New-Generation Biologics Among New Claimants With PsO Across Public Drug Plans in Canada (2018 to 2020) – Sensitivity Analysis 2



PsO = plaque psoriasis.

Blue/solid bars = new-generation biologics; red/striped bars = old-generation biologics. Results by jurisdiction were not feasible due to suppressed data.

Appendix 6: Gross Expenditures of Old-Generation Biologics Beyond LoE for Public Drug Plans Supplemental Analysis

Note that this appendix has not been copy-edited.

Table 6: Public Drug Plan Expenditures on All and New Claimants Since Loss of Exclusivity of Old-Generation Originator Biologics Indicated for PsO – Supplemental Analysis Results

Analysis	Claimants prescribed a biologic for any indication		Claimants with PsO indication only (based on drug-marker algorithm)			
	All claimants	New claimants	All claimants (base case)	All claimants (SA range)	New claimants (base case)	New claimants (SA range)
Supplemental analysis (2014 to 2020)	\$4,341,979,816	\$1,214,075,430	\$135,955,117	\$82,613,690- \$639,163,442	\$30,837,732	\$18,847,685- \$178,877,889

PsO = plaque psoriasis; SA = sensitivity analysis.

Note: Costs do not reflect PLAs between drug plans and manufacturers. The results of this analysis were based on the 2014 loss of exclusivity date for infliximab.