

Cost-Utility Analysis of Roflumilast Cream for Plaque Psoriasis, Including Intertriginous, from the Canadian Societal Perspective

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INTRODUCTION

Background

- Psoriasis is a chronic disease characterized by scaly, often painful skin plaques that is present in about 2% to 4% of the Canadian population.^{1,2}
- Among patients who are treated for psoriasis, most are treated with topical therapies, but some patients who do not respond to topical treatment use high-cost systemic treatments.³
- Historically, topical therapies for the treatment of plaque psoriasis have had numerous limitations in terms of their efficacy, tolerability, and safety for chronic use and in sensitive areas of the body.⁴
- Intertriginous psoriasis, which occurs in skin folds of the body and affects 21-30% of psoriasis patients, has been particularly difficult to treat with topicals in the past.⁴
- Topical roflumilast cream, 0.3%, was developed to fill this unmet need by providing a non-steroidal topical that is safe and effective for the treatment of chronic plaque psoriasis, including being the first indicated for the treatment of intertriginous areas.⁵

Objective

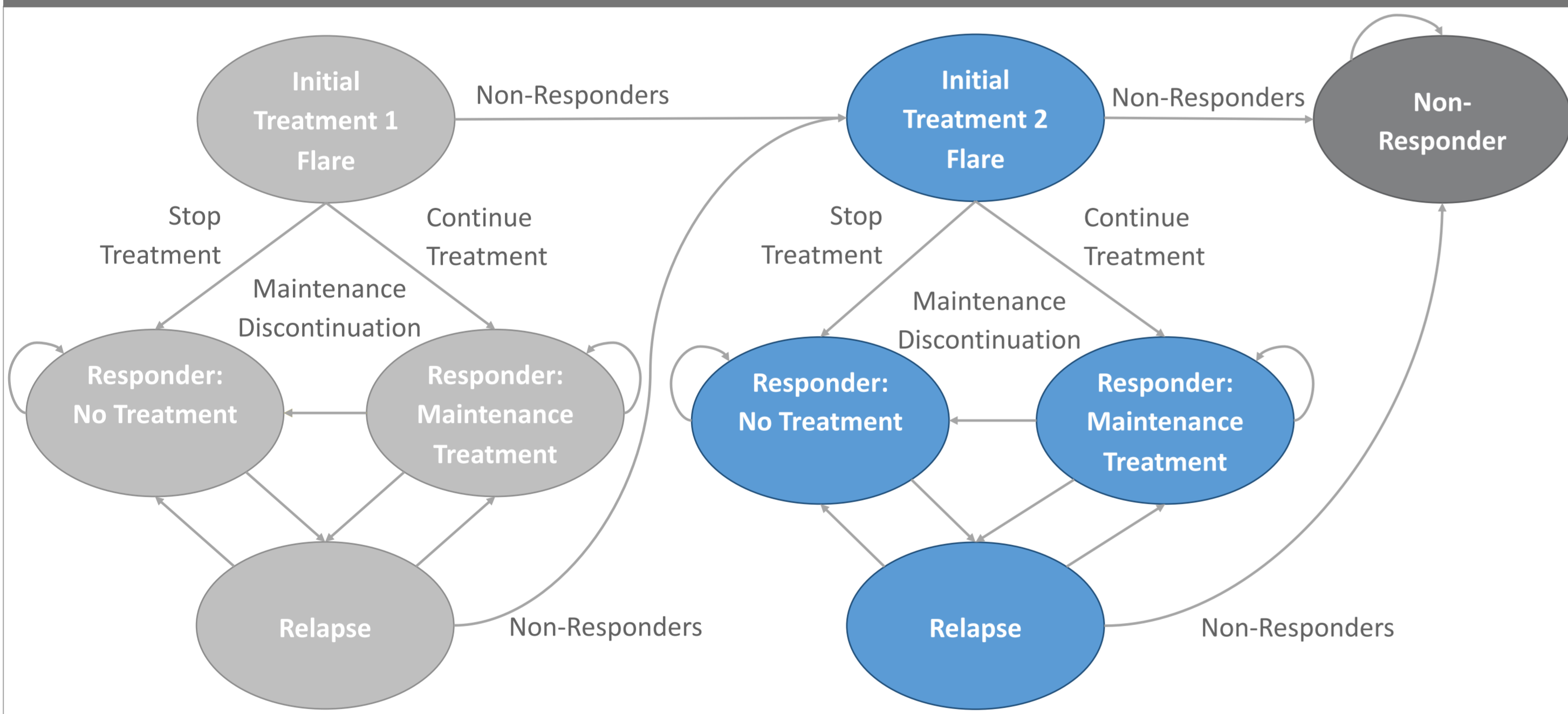
The objective of the cost-utility model was to evaluate the cost-effectiveness of roflumilast relative to current topical treatment options for the treatment of plaque psoriasis from the Canadian societal perspective.

METHODS

Model Summary

- A Markov state-transition cohort model was developed to assess the cost-effectiveness of roflumilast for treating patients with plaque psoriasis over a 5-year time horizon (Figure 1).
- Patients who responded to treatment moved to either the responder without treatment or responder with maintenance treatment health state, depending on whether maintenance treatment is recommended for the treatment they were using. If maintenance treatment was used, patients were assumed to be less likely to relapse in subsequent model cycles until they discontinued maintenance treatment.
- Patients who did not respond to two lines of topical treatments were assumed to receive a market basket of treatment options used by non-responders, including additional topical treatments, oral systemic treatments, and biologic treatments.
- Analyses were conducted for the general plaque psoriasis population and those with intertriginous involvement.
- Comparators included all topical treatments used for psoriasis reimbursed by at least one public drug plan in Canada and were grouped by treatment type.
- Comparator treatment types were not the same in the two analyses, as recommended treatments for intertriginous areas include off-label use since no other topical treatment has data to support an indication for use in intertriginous areas.
- The model was evaluated by averaging output values from a probabilistic analysis for 1000 iterations, which accounted for uncertainty in model parameters.
- Costs and outcomes were discounted at an annual rate of 1.5%.

Figure 1. Model Structure



Model Inputs

- Two network meta-analyses were performed to estimate the comparative efficacy of roflumilast versus alternative topical therapies, one for the general plaque psoriasis population and one for patients with intertriginous involvement (Table 1).
- Utility inputs were derived from existing literature.⁶
- The model included drug acquisition costs (Table 1) and health resource utilization costs from the Ontario Drug Benefit formulary, the Ontario Schedule of Benefits for Physician Services, and the Ontario Schedule of Benefits for Laboratory Services.⁷⁻⁹
- Lost productivity costs were estimated from existing literature and an assumed average hourly wage of \$31.96.^{10,11}

Table 1. Key Model Parameters

Treatment	Probability of Response	4-Week Drug Cost: Flare/Relapse	4-Week Drug Cost: Maintenance
General Plaque Psoriasis Analysis			
Roflumilast	39.9%	\$269.50	\$123.97
Corticosteroid	23.4%	\$28.22	\$0.44
Vitamin D analogue	15.7%	\$123.44	\$27.74
Tazarotene	11.2%	\$92.12	\$39.82
Corticosteroid + Vitamin D analogue	31.1%	\$82.06	\$10.37
Corticosteroid + Tazarotene	34.7%	\$109.35	\$0.52
Intertriginous Psoriasis Analysis			
Roflumilast	69.7%	\$269.50	\$123.97
Corticosteroid	51.4%	\$35.62	\$2.93
Calcineurin inhibitor	50.9%	\$241.24	\$16.32

DISCLOSURES
 KG, WZ, IJ, AS, and SB are consultants for Arcutis Biotherapeutics, Inc. and received grants/research funding; BS and CY are employees of Arcutis Biotherapeutics, Inc.

- REFERENCES**
- Eder L, Widdifield J, Rosen CF, et al. Trends in the Prevalence and Incidence of Psoriasis and Psoriatic Arthritis in Ontario, Canada: A Population-Based Study. *Arthritis Care Res (Hoboken)*. Aug 2019;71(8):1084-1091. doi:10.1002/acr.23743
 - Papp KA, Gniadecki R, Beecker J, et al. Psoriasis Prevalence and Severity by Expert Elicitation. *Dermatol Ther (Heidelberg)*. Jun 2021;11(3):1053-1064. doi:10.1007/s13555-021-00518-8
 - 2018 Addendum to the Canadian Guidelines for the Management of Plaque Psoriasis 2009. *J Cutan Med Surg*. Sep 2016;20(5):375-431. doi:10.1177/1203475416655705
 - Merola JF, Qureshi A, Husni ME. Underdiagnosed and undertreated psoriasis: Nuances of treating psoriasis affecting the scalp, face, intertriginous areas, genitals, hands, feet, and nails. *Dermatol Ther*. May 2018;31(1):e12589. doi:10.1111/dth.12589
 - Leibwohl MG, Kirick LH, Moore AV, et al. Effect of Roflumilast Cream vs Vehicle Cream on Chronic Plaque Psoriasis: The DERMIS-1 and DERMIS-2 Randomized Clinical Trials. *JAMA*. 2022;328(11):1073-1084. doi:10.1001/jama.2022.15632
 - Griffiths CE, Stein Gold L, Cambazaz F, et al. Greater improvement in quality of life outcomes in patients using fixed-combination calcipotriol plus betamethasone dipropionate aerosol foam versus gel: results from the PSO-ABLE study. *Eur J Dermatol*. Jun 1 2018;28(3):356-363. doi:10.1684/ejd.2018.3302
 - Ontario Drug Benefit Formulary/Comparative Drug Index. Accessed January 10, 2023.
 - Schedule of Benefits Physician Services. 2022. October 5, 2022.
 - Schedule of Benefits for Laboratory Services. 2020. July 1, 2020.
 - Strober B, Greenberg D, Kark C, et al. Impact of psoriasis severity on patient-reported clinical symptoms, health-related quality of life and work productivity among US patients: real-world data from the Corrona Psoriasis Registry. *BMJ Open*. Apr 20 2019;9(4):e027535. doi:10.1136/bmjopen-2018-027535
 - Statistics Canada. Table 14-10-0417-01. Employee wages by occupation, annual.

RESULTS

Roflumilast had the lowest costs and highest quality-adjusted life-years (QALYs), dominating all comparator treatments in both analyses.

General Plaque Psoriasis Population Results

- Patients using roflumilast in the general population had \$231 lower costs and 0.006 higher QALYs than the most cost-effective comparator treatment, dominating all comparator treatments.
- Total and incremental costs and QALYs for each treatment type in the general psoriasis population analysis are reported in Table 2.
- Although total drug acquisition costs were approximately 1% higher for roflumilast than corticosteroids alone or in combination, avoided indirect costs related to productivity losses for patients who used roflumilast more than made up for the higher drug costs.

Table 2. Summary of Results in General Plaque Psoriasis Analysis

Treatment	Total Costs	Incremental Costs	Total QALYs	Incremental QALYs
Roflumilast	\$39,874	Reference	4.064	Reference
Corticosteroid + Vitamin D analogue	\$40,105	\$231	4.058	-0.006
Corticosteroid + Tazarotene	\$40,168	\$294	4.058	-0.006
Corticosteroids	\$40,188	\$314	4.058	-0.006
Tazarotene	\$40,552	\$678	4.058	-0.006
Vitamin D analogues	\$40,562	\$688	4.057	-0.007

- Figure 2 displays the scatterplot of incremental costs and QALYs for each model simulation relative to roflumilast and shows in most iterations of the model all treatments had higher costs and lower QALYs than roflumilast.
- The cost-effectiveness acceptability curve (CEAC) in Figure 3 shows roflumilast had more than a 55% chance of being the most cost-effective at all willingness to pay per QALY gained thresholds up to \$200,000.
- A deterministic sensitivity analysis (DSA) was performed, where each model input was varied by 20% in either direction. The only parameter that a 20% change resulted in roflumilast no longer being dominant was if the probability of response for roflumilast was 20% lower, which resulted in an ICER less than \$50,000.

Figure 2. Cost-effectiveness Scatterplot in General Plaque Psoriasis Analysis (vs. Roflumilast)

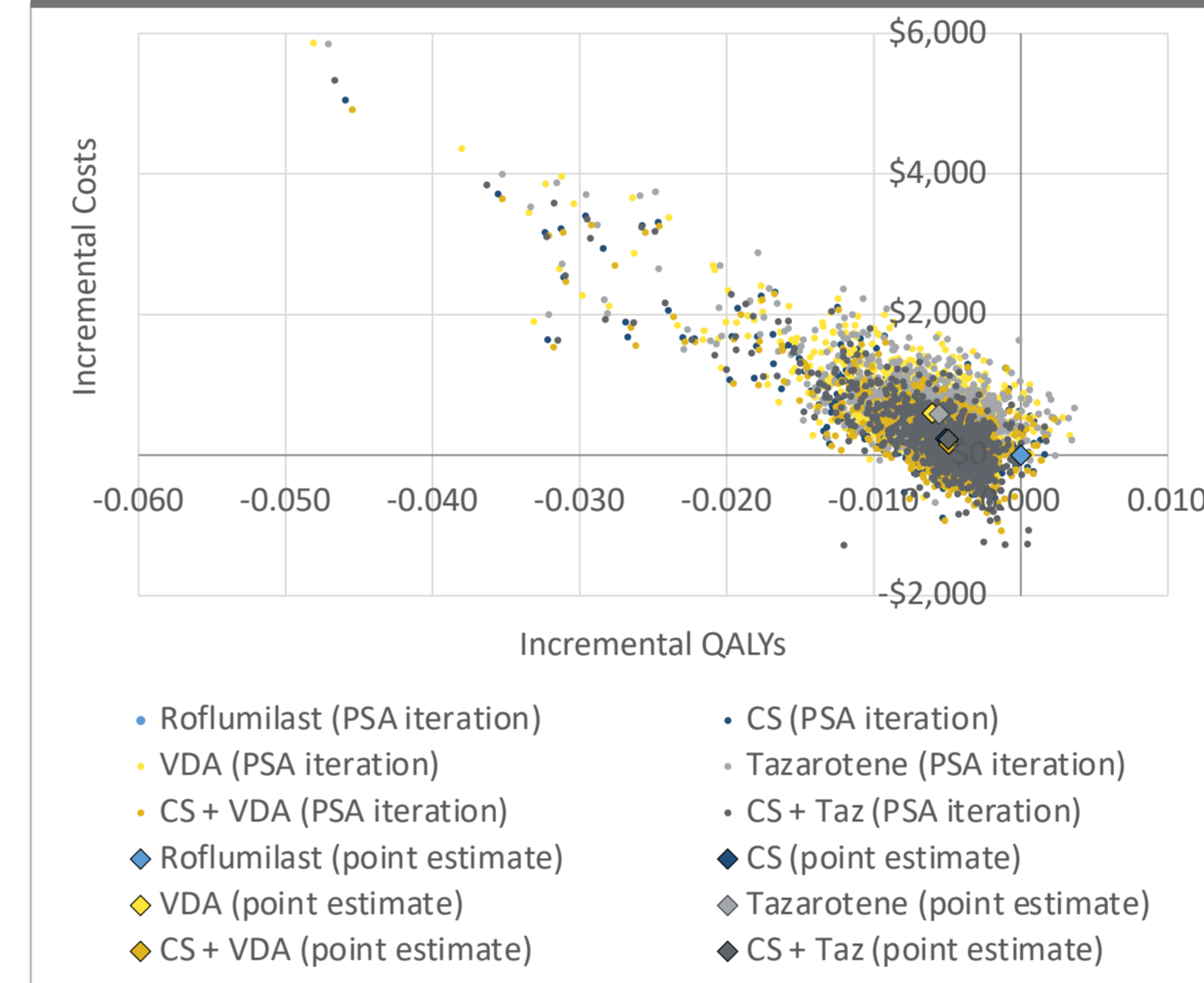
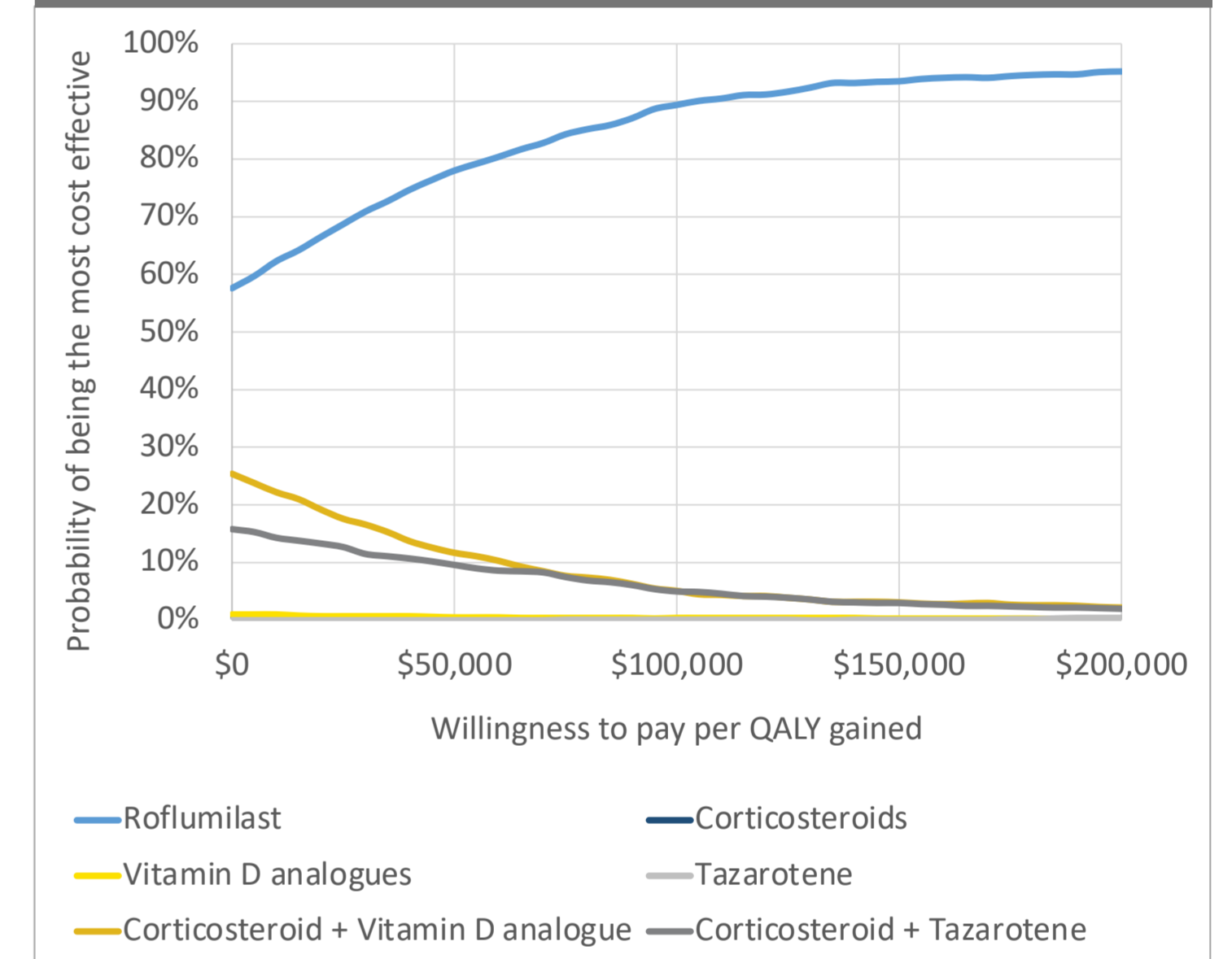


Figure 3. Cost-effectiveness Acceptability Curve in General Plaque Psoriasis Analysis



Abbreviations: CS- corticosteroid, VDA- vitamin D analogue, Taz- tazarotene

Intertriginous Psoriasis Population Results

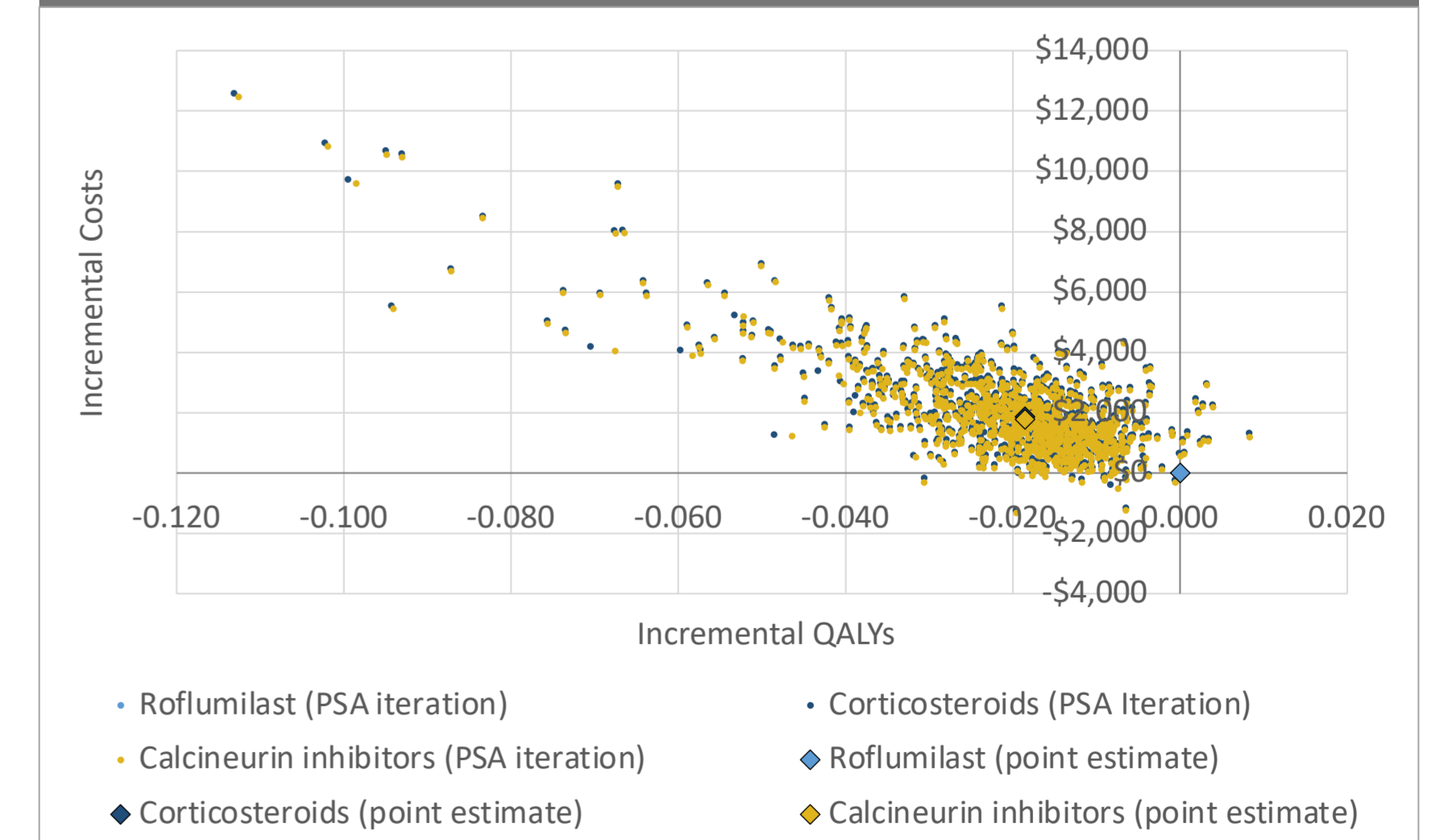
- In the intertriginous analysis, roflumilast dominated all comparator treatments and was even more cost-effective than in the general psoriasis population, with \$1,956 lower costs and 0.021 higher QALYs than the most cost-effective comparator, due to limited treatment options available to these patients.
- Total and incremental costs and QALYs for each treatment type in the intertriginous population analysis are reported in Table 3.
- Roflumilast had the lowest drug costs, HRU costs, and lost productivity costs in the intertriginous analysis.

Table 3. Summary of Results in Intertriginous Psoriasis Analysis

Treatment	Total Costs	Incremental Costs	Total QALYs	Incremental QALYs
Roflumilast	\$36,647	Reference	4.085	Reference
Calcineurin inhibitor	\$38,602	\$1,956	4.064	-0.021
Corticosteroid	\$38,700	\$2,053	4.064	-0.021

- Figure 4 displays the scatterplot of incremental costs and QALYs for each model simulation relative to roflumilast.
- Roflumilast had more than a 95% chance of being the most cost-effective at all willingness to pay per QALY gained thresholds.
- The DSA indicated that no 20% change in any parameter value resulted in roflumilast no longer being dominant in the intertriginous psoriasis analysis.

Figure 4. Cost-effectiveness Scatterplot in Intertriginous Psoriasis Analysis (vs. Roflumilast)



CONCLUSIONS

- Roflumilast is a novel, cost-effective treatment for patients with plaque psoriasis, including intertriginous involvement, in Canada.
- Roflumilast provides a steroid-free topical treatment option that is safe and effective for treatment in all areas of the body and is the first topical treatment to have clinical data to support an indication for intertriginous psoriasis.
- Patients using roflumilast would improve their health-related quality of life, while also lowering costs from the Canadian societal perspective.
- The adoption of roflumilast could lead to patients being able to successfully control their psoriasis with a safe, long term topical treatment, without resorting to the use of immunosuppressive systemics and high-cost biologic therapies.