ECONOMIC EVALUATION OF CABTREO (IDP-126), THE FIRST TRIPLE-COMBINATION FIXED-DOSE TOPICAL GEL FOR THE TREATMENT OF ACNE, FROM THE PERSPECTIVE OF A CANADIAN PAYER

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BACKGROUND

- Acne vulgaris is a chronic inflammatory disorder of the skin[1].
- Acne has a prevalence of 9.38% for all ages and a prevalence of 85% among those 12 to 24 years of age in Canada[2,3].
- Acne has a negative impact on health-related quality of life (HRQoL) likely linked to the high visibility of the disorder. Acne results in significant emotional, psychological, and psychosocial burden on patients which can present as poor self-image, depression and anxiety[4].
- Due to its chronic nature, adolescents will experience acne for many years and a proportion of them will continue to have acne well into adulthood. During this time, patients may try several treatments in attempt to control and resolve the disorder.
- Recent discontinuation of several topical acne treatments in Canada has resulted in a significant gap in the remaining treatments options available to patients.
- CABTREO (IDP-126) is the first triple-combination fixed-dose topical gel consisting of clindamycin (1.2%), adapalene (0.15%), and benzoyl peroxide (3.1%) for the treatment of acne vulgaris.
- Network meta-analysis conducted to assess comparative efficacy of CABTREO suggests that CABTREO numerically superior to other fixed dose monotherapies and topical combination therapies relevant for Canada for both inflammatory and non-inflammatory lesion count reduction.

OBJECTIVES

The objective of this study was to conduct an economic evaluation to estimate the incremental costs and benefits of CABTREO compared to other topical treatments for acne from the perspective of a Canadian payer.

METHODS

Model Overview

- Existing economic models for acne treatments often fail to capture small but clinically meaningful improvements in acne lesion counts. Therefore, a *de novo* Markov state-transition model was developed (Figure 1 and Table 1).
- Health states were defined by the total number of inflammatory and non-inflammatory lesions, capturing changes as small as one lesion within the range of 0 to 200 total lesions.
- Using a 12-week cycle, incremental costs and benefits were assessed for CABTREO and its comparators in Canada over a 60-week time horizon in the base case analysis.
- Some patients were expected to discontinue treatment after 12 weeks due to adverse events, lack of efficacy, or non-adherence.
- Discontinued patients were assumed to switch to and remain in best standard of care (BSC), experiencing a marginal increase in lesion count from baseline.
- In the model, CABTREO was compared to treatment categories instead of individual drugs (Table 1 and Table 2).

Figure 1. Model Structure

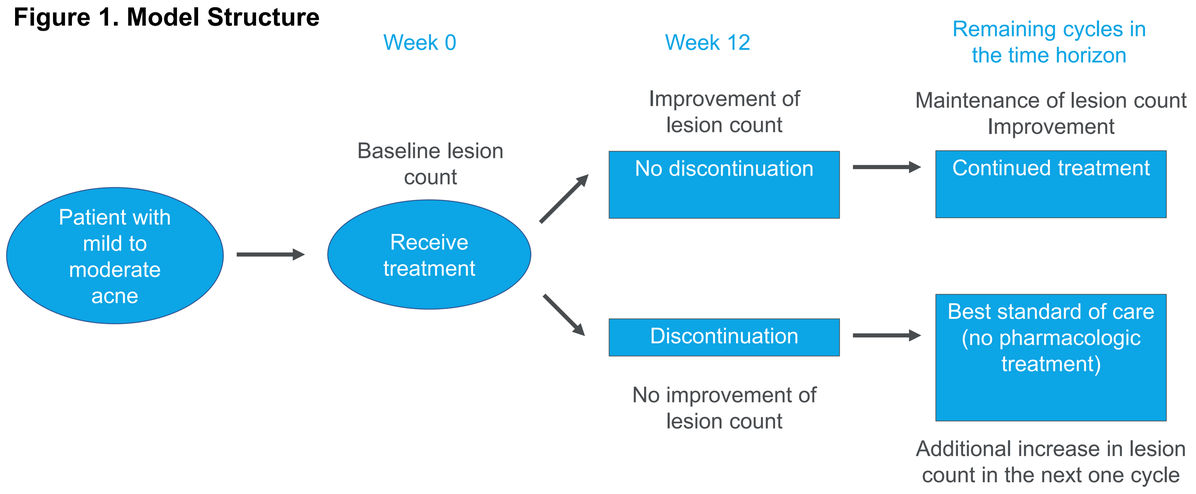


Table 1. Model Parameters

Item	Description
Type of evaluation	Cost-utility analysis
Model type	Markov state transition
Target population	Patients 9 years of age and older with acne vulgaris
Comparators (therapeutic class)	Topical retinoid monotherapy (TMR1) Topical antibiotic monotherapy (TMA1) Topical antibiotic/retinoid fixed-dose combinations (TFDCAR2) Topical retinoid/BPO fixed-dose combinations (TFDCFB2) Topical antibiotic/BPO fixed-dose combinations (TFDCAB2)
Perspective	Canadian payer
Time horizon	60 weeks in the base case
Cycle length	12 weeks
Discounting	1.5% in the base case

Table 2. Comparator Drugs

Comparator	Drugs Included for Cost Calculation
TMR1	ARAZLO, DIFFERIN, DIFFERIN XP, RETIN-A, RETIN-A MICRO, AKILEF
TMA1	TARO-CLINDAMYCIN
TFDCAR2	BIACNA
TFDCRB2	TACTUPUMP, TACTUPUMP FORTE, TARO-ADAPALENE/BENZOYL, TARO ADAPALENE/BENZOYL FT, SANDOZ ADAPALENE/BENZ FT, SANDOZ ADAPALENE/BENZOYL
TFDCAB2	BENZAMYCIN, BENZACLIN, CLINDOXYL, CLINDOXYL ADV, TARO BENZOYL/CLINDA KIT, TARO-CLINDA/BENZOYL PER

Model Inputs and Outputs

- Table 3 presents an overview of input and output items in the model.

Table 3. Overview of input and output items in the model

Inputs			Outputs		
Cost	**Clinical**	**Health utility**	**Cost**	**LY****	**QALY*****
Drug cost	Baseline lesion count	Utility specific to lesion count	On-treatment Drug cost Off-treatment Drug cost	On-treatment LY	On-treatment QALY
Monitoring cost	Change in lesion count		On-treatment monitoring cost Off-treatment monitoring cost	Off-treatment LY	Off-treatment QALY
Indirect cost (lost productivity, transportation, parking)*	All cause discontinuation		On-treatment indirect cost Off-treatment indirect cost		

* Not included in the base case; ** Life-year; *** Quality-adjusted life-year

METHODS (continued)

Clinical Inputs

- Three clinical inputs were used in the model – treatment-specific reduction in lesion count, all-cause discontinuation at 12 weeks, and increase lesion count upon treatment discontinuation.
- Treatment-specific reduction in lesion count was calculated from the absolute reduction in lesion count associated with placebo/vehicle and treatment-specific relative reduction of lesion count estimated from the indirect treatment comparison.
- Increase in lesion count upon treatment discontinuation was obtained from the literature (5).

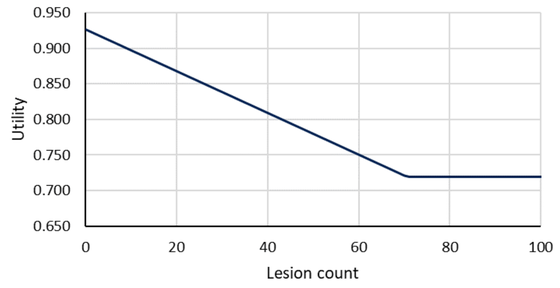
Costs

- Treatment costs were estimated based on the list price of the included drugs, recommended application per day, and their relative market shares based on Canadian claims data.
- Estimates of medical resource use were based on discussion with Canadian dermatologists.
- Indirect costs (when included), captured the lost wages due to medical appointments.

Utilities

- A two-step mapping exercise was developed to link lesion count and EQ-5D (Figure 2).
- First, the association between Dermatology Life Quality Index (DLQI) scores and EQ-5D was estimated using linear regression.
- Second, the association between lesion counts (i.e., the model's health states) and DLQI was established.
- Irrespective of the lesion count, the upper limit of utility was capped at Canadian population norm.
- The lower limit of utility was capped at 0.72 based on published utility value for patients with moderate to severe acne.

Figure 2. Utility vs. Lesion count



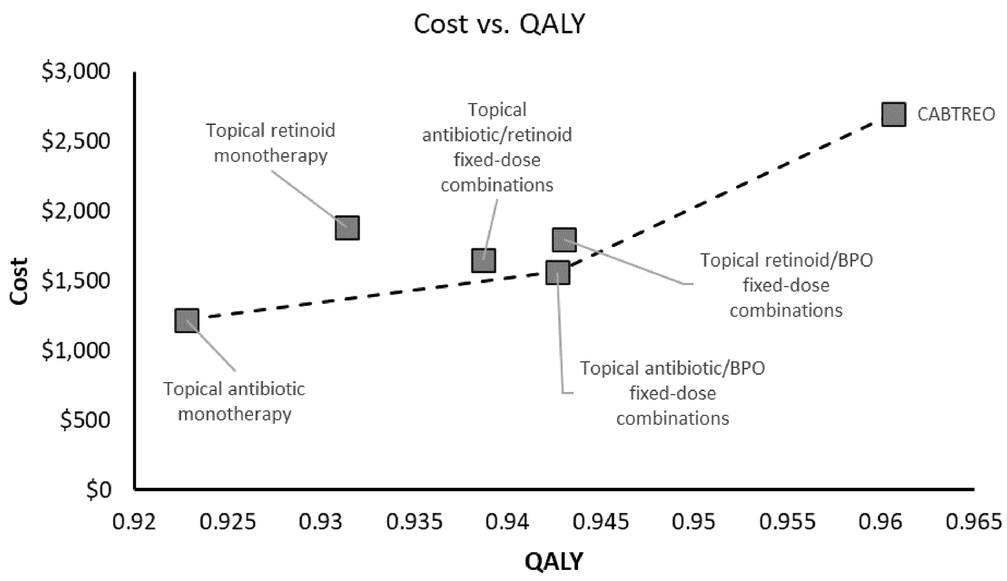
RESULTS

- In alignment with the indirect treatment comparison, the results of the pharmacoeconomic analysis showed that CABTREO offers the highest benefits in terms of QALY (Table 4).
- In the incremental analysis, CABTREO exhibited an ICER of $39,080/QALY compared with the lowest cost comparator TMA1 (Table 4).
- CABTREO exhibited an ICER of $62,967/QALY vs. TFDCAB2 in the sequential analysis (Table 4, Figure 3).

Table 4. Base Case Results of the Probabilistic Analysis

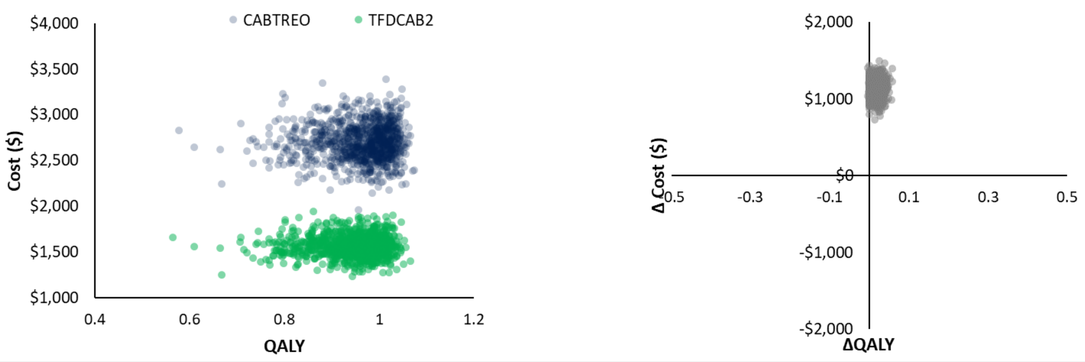
Intervention	Total Cost	Total LY	Total QALY	Incremental Cost vs. Reference	Incremental QALY vs. Reference	ICER vs. Reference	Sequential ICER
TMA1	$1,221	1.150	0.923	Ref	Ref	Ref	Ref
TFDCAB2	$1,567	1.150	0.943	$346	0.020	$17,432	$17,432
TFDCAR2	$1,651	1.150	0.939	$430	0.016	$27,096	Dominated by TFDCAB2
TFDCRB2	$1,795	1.150	0.943	$574	0.020	$28,361	Extendedly dominated by CABTREO
TMR1	$1,887	1.150	0.931	$666	0.009	$77,734	Dominated by TFDCAB2, TFDCAR2, TFDCFB2
CABTREO	$2,700	1.150	0.961	$1,479	0.038	$39,080	$62,967

Figure 3. Cost-Effectiveness Frontier Based on the Probabilistic Analysis



- Figure 4 presents the absolute and incremental cost and QALY for CABTREO and TFDCAB2.
- The results suggest consistent relative clinical benefit for CABTREO over 1,000 iterations.

Figure 4. Probabilistic Iterations



CONCLUSIONS

- The economic model developed in this study can capture small but clinically meaningful changes in total lesion count associated with acne treatment.
- CABTREO provides the greatest benefits in terms of QALY for the treatment of acne vulgaris among the intervention considered in the analysis, resulting in a very favourable ICER.
- CABTREO fulfils an unmet need in acne topical therapies by providing an optimized drug concentration delivered via a novel delivery mechanism in a cost-effective manner.

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