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#### **BACKGROUND**

- The Canadian Agency for Drugs and Technologies in Health (CADTH) evaluates therapies for safety, efficacy and cost-effectiveness, then provides participating plans with a funding recommendation.
- Cost-effectiveness is evaluated through a reassessment of the manufacturers' submitted economic model to generate CADTH-based incremental cost-effectiveness ratios (ICERs), and a subsequent recommended required discount to achieve cost-effectiveness based on CADTH's willingness-to-pay (WTP) threshold (also known as price reduction statements).
- Post-CADTH, therapies then enter the pCPA process with the aim of concluding negotiations with a letter of intent (LOI) leading to listing on provincial formularies.

#### **OBJECTIVE**

This study aims to assess how CADTH's reassessments of oncology and rare disease therapies' ICERs impact the outcomes of price negotiations with the pan-Canadian Pharmaceutical Alliance (pCPA).

#### **METHODS**

- All publicly available CADTH recommendations for rare disease and oncology drugs from Q3 2017 to Q2 2022 were identified and reviewed for the submitted and reanalyzed ICERs, as well as price reduction statements.
- This was then cross-referenced with the drug's pCPA negotiation status and negotiation outcome.
- Qualitative analysis was then conducted to understand the main drivers of the recommendations and outcomes.

#### **RESULTS**

# **Figure 1.** Decision tree for identifying relevant submissions

# All submissions Q3 2017 – Q2 2022 were identified

Filtered for submissions in the "oncology" and "rare disease" therapeutic areas

Final: RD: 36 submissions Oncology: 140 submissions

#### MOST RARE DISEASE AND ONCOLOGY DRUGS RECEIVED A POSITIVE CADTH OUTCOME

- A total of 36 rare disease (RD) and 140 oncology drugs were identified. (Figure 1)
- 97% (n = 35 of 36) of RD and 79% (n = 111 of 140) of oncology drugs received a positive funding recommendation from CADTH.
- Lonsurf and Tecentriq received negative CADTH recommendations but still obtained an LOI from pCPA
- Multiple therapeutics received negative CADTH recommendations but are still under consideration for pCPA negotiations

#### PCPA NEGOTIATIONS

- On average, RD (n = 22) and oncology (n = 93) drugs that obtained a pCPA LOI took 8.8 and 9.1 months, respectively, from their CADTH recommendation.
- Price reduction statements did not seem to have an impact on the time it took to negotiate an LOI, p > 0.05 for both groups (Table 1).
- Average pCPA negotiations lasted 9.1 months from the final CADTH recommendation (Figure 2).
- 2 oncology drugs that were deemed 'not cost effective' by CADTH still obtained LOIs
- HTA outcomes yielding unrealistic discount statements can still lead to LOIs, raising questions about the role of these statements in confidential pricing negotiations

Table 1. Time to an LOI with pCPA

Price Reduction Statement	Rare Disease Therapeutics	Oncology Therapeutics
< 90%	8.8 months, (n = 10)	7.1 months, (n = 31)
≥ 90%	7.9 months, (n = 9)	9.8 months, (n = 6)
P-value	0.2002	0.6523

Note: 3 of 22 RD and 56 of 93 oncology therapeutics that received a LOI did not include a specific price reduction statement

# **Figure 2.** Timeline from CADTH recommendation to pCPA LOI

Positive CADTH Recommendation

3.3 Months

pCPA Negotiation Begins

5.8 Months

pCPA Decision

Average Total Negotiation Period: 9.1 months

#### **CADTH REANALYZED ICERS: RARE DISEASE**

- The average difference between submitted and recalculated ICER is 276%.
- All RD products (n = 12 of 12) with a price reduction statement ≥ 90% received a positive recommendation (Table 3).
- CABLIVI received a negative recommendation but still received a price reduction statement, outlining a 55%-75% reduction.

**Table 3.** pCPA negotiation status of therapeutics with CADTH price reduction statements ≥ 90%

pCPA Negotiation Status	Rare Disease Therapeutics	Oncology Therapeutics
LOI	75% (n = 9 of 12)	46% (n = 6 of 13)
Ended without agreement	0% (n = 0 of 12)	0% (n = 0 of 13)
Chose not to negotiate	0% (n = 0 of 12)	0% (n = 0 of 13)
Ongoing	25% (n = 3 of 12)	38% (n = 5 of 13)
Under consideration for negotiation	0% (n = 0 of 12)	15% (n = 2 of 13)

**Table 2.** Final CADTH recommendations of therapeutics with price reduction statements above and below 90%

<b>Product Area</b>	Price Reduction Statement	Average Difference Between Submitted and Reanalysis ICERs <sup>1</sup>	Positive CADTH Recommendations <sup>2</sup>
Oncology	< 90%	280% (n = 33)	93% (n = 38 of 41)
Oncology	≥ 90%	404% (n = 16)	65% (n = 13 of 20)
Rare Disease	< 90%	371% (n = 13)	94% (n = 17 of 18)
Rare Disease	≥ 90%	138% (n = 9)	100% (n = 12 of 12)

<sup>1</sup>Therapeutics without a specific submitted ICER and a specific reanalysis ICER were not included

<sup>2</sup>Therapeutics without a specific price reduction statement were not included

#### **CADTH REANALYZED ICERS: ONCOLOGY**

- The average difference between submitted and recalculated ICER is 320%.
- 65% (n = 13 of 20) of oncology products with a price reduction statement ≥ 90% received a positive recommendation.

## ABBREVIATIONS AND ACRONYMS

CADTH = Canadian Agency for Drugs and Technologies in Health ICER = Incremental Cost-Effectiveness Ratio LOI = Letter of Intent pCPA = pan-Canadian Pharmaceutical Alliance RD = Rare Disease WTP = willingness-to-pay

## CONCLUSIONS

- Despite significant differences in the manufacturer submitted and reanalysis ICERs, almost all RD therapies were able to achieve a successful outcome with CADTH and to negotiate successfully with pCPA.
- Oncology drugs were numerically less likely to receive a positive recommendation, but had fewer price reduction statements exceeding 90%.
- Oncology therapeutics that received price reduction statements ≥ 90% were less successful than RD therapies that received ≥ 90% price reduction statements at completing negotiations with pCPA.
- 97% (n = 35 of 36) of RD and 79% (n = 111 of 140) of oncology drugs received a positive recommendation from CADTH.
- Of drugs that entered pCPA, 75% (n = 9 of 12) of RD and 46% (n = 6 of 13) of oncology drugs successfully obtained an LOI
- On average, RD drugs and oncology drugs that successfully obtained an LOI from pCPA took 8.8 months and 9.1 months to negotiate.
- Further research is needed to understand the discrepancy between the success of RD drugs and oncology drugs, particularly those with significant price reduction statements.



