HTA43

Review of Combination Oncology Regimens in Canada – Do complexities of multi-therapy submissions impact reimbursement outcomes?

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BACKGROUND

- The Canadian Agency for Drugs and Technologies in Health (CADTH) assesses drug submissions for their safety, efficacy and cost-effectiveness to then issue a positive or negative recommendation for funding.
- The pan-Canadian Pharmaceutical Alliance (pCPA) negotiates with pharmaceutical companies to lower drug costs and issues a letter of intent for reimbursement
- The frequent launches of complex oncology regimens results in health technology assessment agencies and payers having to deal with the dynamics of multiple manufacturer involvement within a single evaluation.
- All publicly available combination oncology regimens assessed by CADTH from Q3 2017 to Q1 2023 were included

OBJECTIVE AND METHODS

This study aims to assess the dynamics of combination oncology regimen submissions to CADTH and the subsequent payer negotiations through pCPA.

IDENTIFYING RELEVANT SUBMISSIONS

- Combination regimens from oncology indications assessed by CADTH over the past five years (i.e. Q3 2017 to Q1 2023) were included.
- Submissions were reviewed to determine whether one or both manufacturer were involved in the CADTH submissions and to assess the dynamics of confidential pCPA pricing negotiations.
- Positive and negative recommendations and negotiations were sourced from CADTH and pCPA.
- Price reduction statements were sourced from CADTH.
- CADTH re-analyzed versus the manufacturer submitted ICERs were calculated as actual/submitted minus 100%

RESULTS

ALL THE SUCCESSFUL CADTH SUBMISSIONS HAD PRICE REDUCTION STATEMENTS

- A total of 33 CADTH oncology combination regimen submissions were identified over the past 5 years (Q3 2017 – Q1 2023).
- 27 obtained positive recommendations from CADTH (**Figure 1**)
- All 27 submissions that received a positive recommendation included a price reduction statement (**Figure 2**)

SUBMISSIONS WITH HIGH PRICE REDUCTION STATEMENTS STILL NEGOTIATED SUCCESSFULLY

- 18 of the 27 successful submissions included specific price reduction statements (**Figure 2**)
- 7 of the 18 submissions had a price reduction statement citing a ≥95% price reduction
- 5 of those 7 completed pCPA negotiations,
  - 4 signed a Letter on intent (LOI), and 4 of the 4 obtained funding in at least 1 province
  - 1 did not pursue negotiations (**Table 1**)
- The 6 (of 33 total) combination submissions with negative recommendations had either an unspecified or 99% reduction statement (**Figure 3**)
- The average difference between the submitted and the reanalyzed ICERs was >300%

MOST COMBINATION REGIMEN FILES WERE LED BY ONE MANUFACTURER

- Only 8 of the 33 submissions contained multi-manufacturer combination therapies
- The remaining 25 contained generics or were from the same company
- All 8 companies have initiated confidential pricing (pCPA) negotiations, of those 8, only 1 was led by both companies (**Table 2**)
  - Pembrolizumab + Lenvatinib (PC0288)

Figure 1. Flow chart of combination oncology submissions to CADTH and pCPA and their accompanying price reduction statements

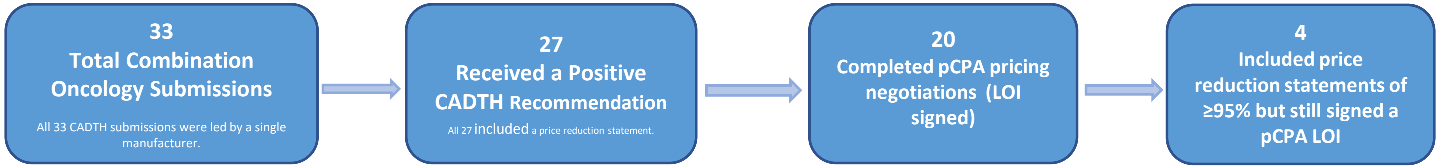


Table 1. Regimens with a ≥95% price reduction statement and their pCPA conclusion.

	Combination Products	Price Reduction Statement	pCPA Conclusion
1.	Braftovi and cetuximab	99%	LOI
2.	Darzalex with bortezomib, melphalan and prednisone	95%	LOI
3.	Darzalex with lenalidomide and dexamethasone	95%	LOI
4.	Tecentriq & Avastin	99%	Negotiations not pursued
5.	Tecentriq & Avastin	99%	LOI

Figure 2. The distribution of price reduction statements of regimens that obtained positive CADTH recommendations, n = 27

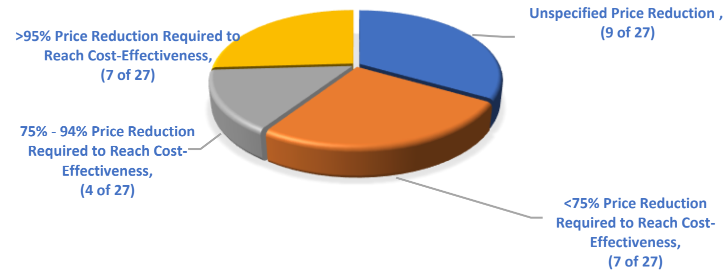
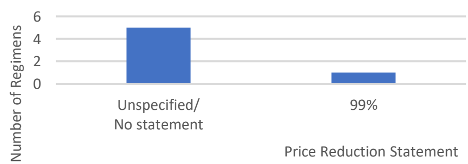


Table 2. Combination regimens' manufacturer(s) in pCPA negotiations

22 of 27 regimens with positive recommendations signed LOIs or are actively negotiating	
14 single manufacturer regimens	8 multi-company regimens • 7 of the 8 were led by the submitting manufacturer • 1 of the 8 was a multi-company negotiations, led separately by both manufacturers

Figure 3. Price reduction statements of regimens with negative CADTH recommendations, n=6



REGIMENS UNSUCCESSFUL WITH PCPA HAD VARYING PRICE REDUCTION STATEMENTS

- 24 of the 27 positive recommendations have completed pCPA negotiations as of March 2023
- 20 of those 24 regimens signed a LOI from pCPA
- The 4 regimens that did not sign LOIs had varying price reduction statements (**Table 3**)

Table 3. Regimens with unsuccessful pCPA negotiations

Combination Product/Regimen	Price Reduction Statement
Inqovi	15%
Pomalyst with dexamethasone and bortezomib	Unspecified amount
Tafinlar and Mekinist	88%
Verzenio with an aromatase inhibitor or with fulvestrant	Unspecified amount

CONCLUSIONS

- Although the evaluation of combination oncology regimens can involve greater complexities than a single regimen review, the majority assessed did result in a positive outcome with CADTH and were able to achieve a successful confidential pricing negotiation with pCPA.
- Despite significant and unrealistic price reduction statements, regimens were able to navigate successfully with both CADTH (82%, n = 27 of 33) and pCPA (67%, n = 21 of 30 completed files)
- 8 combination regimens involved brand name drugs from different manufacturers, all of which have initiated pCPA negotiations. 7 of these 8 negotiations were led by the submitting manufacturer.
- Most recently, the remaining pCPA negotiation involved both manufacturers potentially signaling a change in policy or process.
- The inconsistency regarding singular or multi-manufacturer involvement in pCPA negotiations could signal an evolving process or policy that may be influenced by factors not yet clearly or transparently defined.

DISCLOSURES

Liovas, A. and Privolnev, Y. are employed by IPSEN Pharmaceuticals Canada. At the time of the analysis, Pan, V. and Jakac-Sinclair, N. were employed by PIVINA Consulting Inc., which has contracts with multiple pharmaceutical companies.