Average Time to Patient Access From Drug Approval: An Analysis of Ontario & Quebec

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Background

The *Canadian Agency for Drugs and Technologies in Health (CADTH)* is responsible for reviewing the clinical- and cost-effectiveness of oncology drugs via the pan-Canadian Oncology Drug Review (pCODR)[1].

> The pan-Canadian Oncology Drug Review (pCODR), a CADTH program, assesses cancer drugs and makes reimbursement recommendations to the participating federal drug plans, provincial and territorial Ministries of Health (excluding Quebec), and provincial cancer agencies to guide their funding decisions. pCODR is designed to bring consistency and clarity to the assessment of cancer drugs by looking at clinical evidence, cost-effectiveness, and clinician and patient perspectives.
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> *-CADTH pCODR Operational and Performance Metrics Report, 2016, p. 4*

pCODR launched in July 2011[1]. As of March 31, 2016, pCODR had issued a total of 65 recommendations[1]. Of the 65 oncology drugs reviewed by March 31, 2016, 14% had positive recommendations, 65% conditional recommendations, and 21% had negative recommendations[1]. The percentage of cancer drugs receiving positive recommendations without conditions has consistently declined each year over the time period, dropping from 25% of products recommended without conditions in 2011 down to 5% in 2015 and none during the first months of 2016[2] (**Figure 1**; **Figure 2**).

All provinces (with the exception of Quebec) turn to pCODR's recommendations for guidance when determining if an oncology drug should be publically listed. However, a positive pCODR recommendation does not guarantee subsequent provincial listing as each province makes independent coverage decisions, with the pCODR recommendations being one of the elements that go into the decision process.

In Quebec, oncology drugs are similarly evaluated by the Institut national d'excellence en santé et en services sociaux (INESSS)[3] and public coverage is provided by Régie de l'assurance maladie du Québec (RAMQ)[4] based on INESSS recommendations.

Objectives

The objective of this study was to determine the average time from Health Canada approval to provincial reimbursement in Ontario and Quebec for novel oncology drugs. Time to first private claim will also be assessed as a comparison.

The focus is on Ontario and Quebec since they represent two different drug evaluation systems (ie – pCODR and INESSS) within the Canadian context and have a combined population of 22 309 100, which comprises 61% of the Canadian population[5].

Methods

Health Canada's "Notice of Compliance (NOC)" database was used to identify the date of "new active substances" in oncology approved from January 1, 2012 until December 31, 2016[6]. The NOC database contains the Health Canada authorization dates for all drugs dating back to 1994 that have received an NOC[6].

For public reimbursement data in Ontario, the pan-Canadian Oncology Drug Review (pCODR) was used to determine the date of listing for each drug[7]. The "Provincial Funding Summary" publicly reports the funding date by each participating province for each drug that has completed the pCODR review process. The *Exceptional Access Program (EAP)*[8] drug list in Ontario was used to identify any publicly funded drugs that were not captured via pCODR's "Provincial Funding Summary."

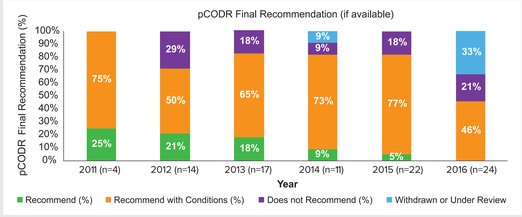
For listing data in Quebec, the Institut national d'excellence en santé et en services sociaux (INESSS) was used to determine the date of listing for each drug[3]. Additionally, the funding dates listed on the INESSS website were validated with the *Liste des médicaments fournis en établissements* published periodically by the Régie de l'assurance maladie du Québec (RAMQ)[4].

Prescription claims from a private pay-direct drug plan database that includes all major insurance providers in Ontario and Quebec were provided by QuintilesIMS to determine the date of first private claim. During the study period, approximately 86% and 90% of all private direct pay activity in Ontario and Quebec, respectively, are captured in the QuintilesIMS claims data[9].

Results

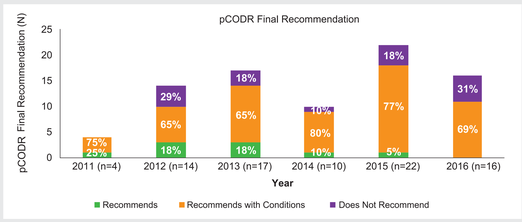
- 43 oncology drugs met inclusion criteria (**Table 1**).
- As of January 2017, Ontario had listed 23/43 (53%) and Quebec had listed 21/43 (49%) of the drugs (**Figure 3**).
- Of the listed drugs, the median time from NOC to provincial listing was 382 days (IQR=239-523) in Ontario and 367 days (IQR=234-722) in Quebec (**Table 2**).
- The median time to first private claim from NOC was 84 days (IQR=46-141) and 127 days (IQR=88-213) in Ontario and Quebec, respectively (**Table 3**).
- Of the drugs with a negative review by pCODR, 12% had listing in Ontario as of January 2017.
- In Ontario, all the drugs with private claims (n=34) had a first private claim prior to the public listing date.
- In Quebec, first private claims for two of the 31 drugs with private claims data (brentuximab, vemurafenib) occurred after public listing.
  - In the case of brentuximab, it has two Health Canada approved indications: Hodgkin lymphoma and systemic anaplastic large cell lymphoma (sALCL). At the time of the first private claim (March 2014), only sALCL was publically covered in Quebec, so it is possible the claim was for a patient with Hodgkin lymphoma.
  - In the case of vemurafenib, it is less clear why a first private claim was submitted in Dec 2012 after public listing in Nov 2012.
- 9/43 (21%) drugs received no private claims in Ontario during the study period
  - 7/9 (78%) of those without a private claim were injectables.
- 12/43 (28%) drugs received no private claims in Quebec during the study period
  - 9/12 (75%) of those without a private claim were injectables.

Figure 1. Proportion of pCODR Recommendations without Conditions is showing a Declining Trend Between 2011 and 2016.



Adapted from PharmaFocus 2021 Industry Briefing[2]. *There were 68 drugs reviewed between 2011-2016, but two were resubmissions (regorafenib and crizotinib) and 1 was withdrawn (bendamustine).

Figure 2. Number of pCODR Recommendations without Conditions is showing a Declining Trend Between 2011 and 2016.



**There were 67 drugs reviewed and given a final recommendation between 2011-2016, but two were resubmissions (regorafenib and crizotinib) for the same indication.

Figure 3. Public Listing Status in Ontario and Quebec as of Jan 2017.

Table 1. Oncology Drugs Receiving NOC between January 2012 and December 2016.

Trade Name	Chemical Name	Trade Name	Chemical Name
Adcetris	brentuximab	**Lynparza**	olaparib
Alecensaro	alectinib	**Mekinist**	trametinib
Arzerra	ofatumumab	**Ninlaro**	ixazomib
Blincyto	blinatumomab	**Opdivo**	nivolumab
Bosulif	bosutinib	**Perjeta**	pertuzumab
Caprelsa	vandetanib	**Pomalyst**	pomalidomide
Cotellic	cobimetinib	**Stivarga**	regorafenib
Cyramza	ramucirumab	**Sylvant**	siltuximab
Darzalex	daratumumab	**Tafinlar**	dabrafenib
Erivedge	vismodegib	**Tagrisso**	osimertinib
Gazyva	obinutuzumab	**Treanda**	bendamustine
Giotrif	afatinib	**Trisenox**	arsenic trioxide
Ibrance	palbociclib	**Venclexta**	venetoclax
Iclusig	ponatinib	**Xalkori**	crizotinib
Imbruvica	ibrutinib	**Xofigo**	radium-223
Inlyta	axitinib	**Xtandi**	enzalutamide
Istodax	romidepsin	**Yervoy**	ipilimumab
Jakavi	ruxolitinib	**Zaltrap**	aflibercept
Kadcyla	trastuzumab	**Zelboraf**	vemurafenib
Keytruda	pembrolizumab	**Zydelig**	idelalisib
Kyprolis	carfilzomib	**Zykadia**	ceritinib
Lenvima	lenvatinib		

Table 2. Time (Days) from NOC to Public Listing in Ontario & Quebec.

Metric	Ontario (n=23)	Quebec (n=21)
Median	382	367
Range (min, max)	(134, 817)	(188, 1008)
Interquartile Range (25%, 75%)	(239, 523)	(234, 722)

Table 3. Time (Days) from NOC to First Private Claim in Ontario & Quebec.

Metric	Ontario (n=34)	Quebec (n=31)
Median	84	127
Range (min, max)	(13, 411)	(45, 665)
Interquartile Range (25%, 75%)	(46, 141)	(88, 213)

Conclusions

- The median days from NOC to provincial listing was similar between Ontario and Quebec.
- Private insurance plans continue to reimburse novel oncology treatments in a shorter timeframe than public programs.
- There was a trend that time to first private claim in Quebec was longer than that in Ontario, which needs to be investigated further as time to first private claim could be impacted by various confounding factors.
- A limitation of this study is that access to drugs via clinical trial, compassionate usage and pharma-sponsored programs would not be captured.

References

[1] Canadian Agency for Drugs and Technologies in Health. *CADTH pCODR Operational and Performance Metrics Report: Updated March 31, 2016*. Ottawa, ON: CADTH; 2016.
[2] QuintilesIMS. (2017). PharmaFocus 2021 Industry Briefing.
[3] Institut national d'excellence en santé et en services sociaux. (2017). Retrieved from: http://www.inesss.qc.ca/index.php?id=42
[4] Régie de l'assurance maladie du Québec. (2017). Retrieved from: http://www.ramq.gouv.qc.ca/fr/Pages/accueil.aspx
[5] Statistics Canada. (2016). Retrieved from: http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/demo02a-eng.htm.
[6] Health Canada. (2017). Retrieved from: https://health-products.canada.ca/noc-ac/index-eng.jsp.
[7] CADTH. (2017). Retrieved from: https://www.cadth.ca/pcodr/find-a-review.
[8] Ministry of Health and Long-term Care Ontario. (2016). Retrieved from: http://health.gov.on.ca/en/pro/programs/drugs/pdf/frequently_requested_drugs.pdf
[9] QuintilesIMS. (2017). PharmaStat.