

2025 EDITION

MORSE CONSULTING'S

Canadian Reimbursement & Forecasting Timeline Report

A comprehensive source of reimbursement timelines and insights to inform forecasting and planning needs.

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CRAFT REPORT OUTLINE

Section

Executive Summary

Market Access Timelines

HTA Metrics

pCPA Metrics

- pCPA Initiation
 - pCPA Completion
 - pCPA Closed Files
 - pCPA Not Negotiated
 - TNP
-

Jurisdictional Funding

- All Files
 - Oncology Files
 - Non-Oncology Files
-



CRaFT 2025: EXECUTIVE SUMMARY

Average Time from CDA submission to First Provincial Listing

X Days

Oncology drugs

X Days

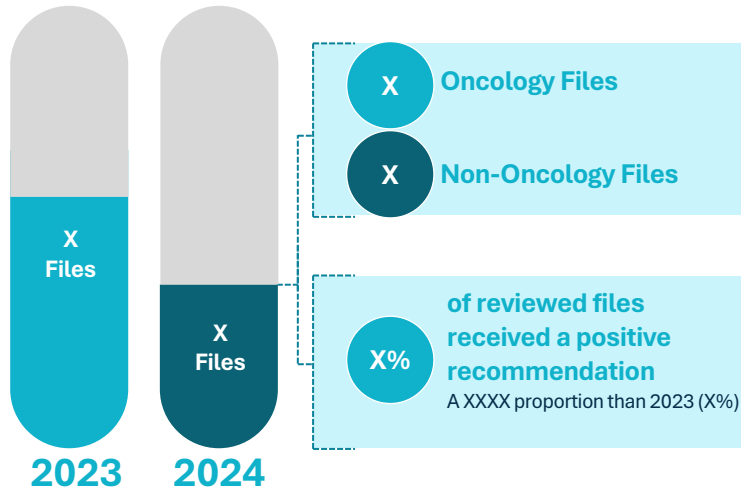
Non-Oncology drugs

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While overall timelines have remained relatively stable, notable trends have emerged within each stage of the reimbursement process:

HTA Reviews

CDA reviewed X files in 2024 than 2023



Introduction of Time-Limited Reimbursement Recommendations

- Demonstrates...

Alignment between CDA and INESSS recommendations XXXX to X% in 2024

- May indicate

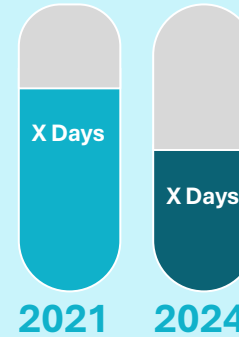
pCPA Negotiations

X Files
Concluded with a Letter of Intent (LOI)
X% reduction in average negotiation time since 2021

X Files
Closed by the pCPA Without an LOI
X were XXXX, a higher volume than seen in any prior year.

X Days
Average Time Under pCPA Consideration
X% increase since 2021

Time from Final CDA Recommendation to pCPA LOI Decreased



Based on MORSE's methodology and assumptions, the Targeted Negotiation Process (TNP), while potentially expediting timelines, demonstrated a lower success rate (X%) compared to non-TNP files (X%) in terms of reaching an agreement.

Provincial Funding

Large Interprovincial Timing Variability

Average time to funding post-LOI ranged from X days (XX) to X days (XX) for files that Completed pCPA negotiations in 2024

XX & XX Consistently Fund Fewer Drugs

Only X% and X% of drugs Completed in 2024 were funded, respectively, compared to the national average of X%.

Certain Provinces Fund Non-Oncology Drugs Faster than Oncology Drugs

(XX, XX, XX), while others show no clear pattern or the opposite trend (e.g., XX).

Average Time to Funding Has Generally XXXX

For most provinces in recent years, although some variation exists based on drug type (oncology vs non-oncology).

Minimum funding timelines demonstrate the potential for rapid provincial funding under optimal conditions.

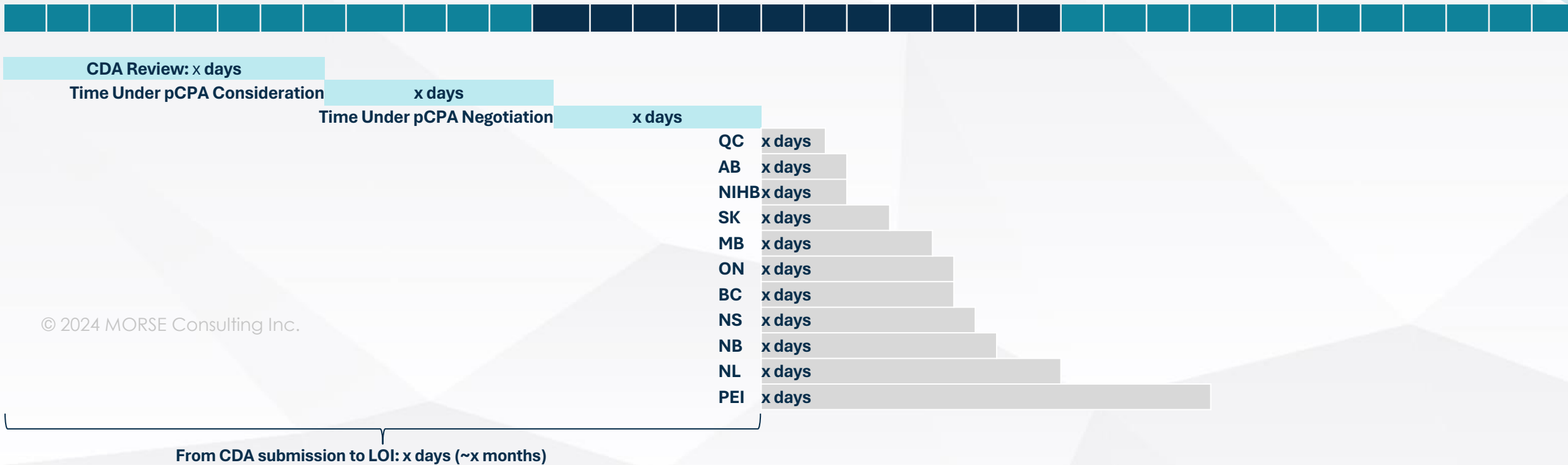
CRaFT Report: Note the current slide is for illustrative purposes. The executive summary includes multiple slides highlighting key report takeaways with data labels.

CRaFT DRD Sub-Report: Note the current slide is for illustrative purposes and the same analysis is performed for DRD files in the DRD Sub-Report

MARKET ACCESS TIMELINE FOR ONCOLOGY DRUGS

The average time between CDA submission and first provincial funding is **x days (~x months)**.

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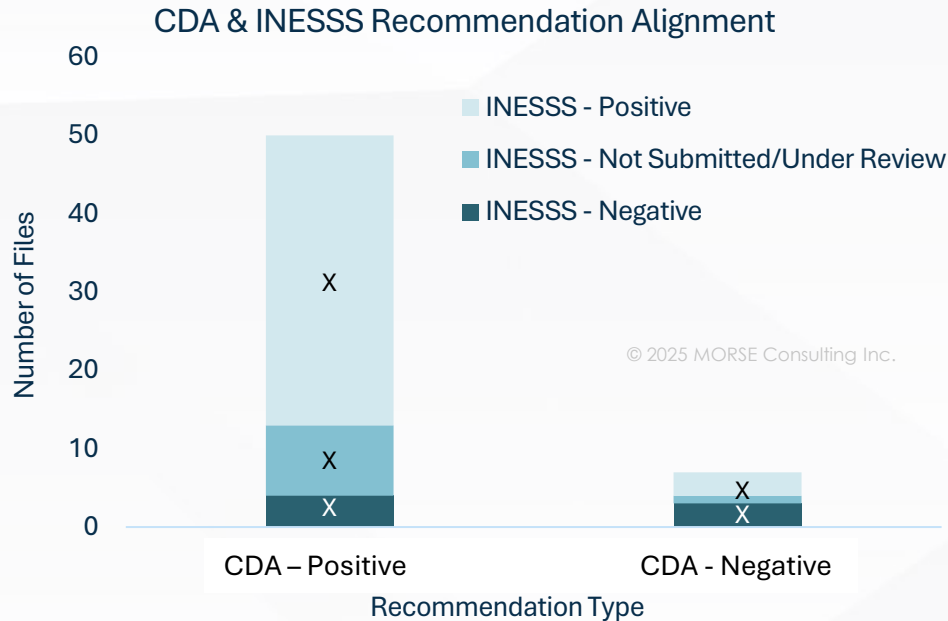
CRaFT Report: Note the current slide is for illustrative purposes. The analysis is performed for **Oncology** and **Non-Oncology** files with data labels in the CRaFT Report.

CRaFT DRD Sub-Report: Note the current slide is for illustrative purposes and the same analysis is performed for **DRD** files in the DRD Sub-Report



CDA & INESSS ALIGNMENT – 2024

X% of files reviewed by CDA in 2024 had aligned recommendations with INESSS, XXXX than 2023 when X% had aligned recommendations. Of the remaining 2024 files, X% were misaligned and X% had not yet been reviewed by, or submitted to, INESSS.



Note:

- CDA – Positive includes files that received ‘Reimburse with conditions’ and ‘Reimburse’ recommendations; CDA – Negative includes files that received ‘Do not reimburse’ recommendations.
- INESSS – Positive includes files that received ‘Registration - With conditions’, ‘Registration’, and ‘Refusal to list unless conditions were met’; INESSS – Negative includes ‘Refusal of registration’.
- Some of these recommendations may have been reconsidered by CDA or INESSS since the MORSE data cut off

Files that received a positive recommendation from CDA and a negative recommendation from INESSS (n=X)

Drug Name	Indication	Type
XXX	XXX	Non-Oncology
XXX	XXX	Oncology
XXX	XXX	XXX
XXX	XXX	XXX

Files that received a negative recommendation from CDA and a positive recommendation from INESSS (n=X)

Drug Name	Indication	Type
XXX	XXX	XXX
XXX	XXX	XXX
XXX	XXX	XXX
XXX	XXX	XXX

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CRaFT DRD Sub-Report: Note the current slide is for illustrative purposes and the same analysis is performed for **DRD** files in the DRD Sub-Report

pCPA INITATION: TIMELINE

The overall average time under consideration in 2024 was X days, representing a X% XXXX over 2023 and a X% XXXX since 2021.

Time Under pCPA Consideration for Initiated Files by Year and Type
(Average)



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pCPA INITIATION: TIMELINE OUTLIERS

Similarities can be found among both the “Slow Outlier” and “Fast Outlier” categories.

Slow Outliers (n=5)			
Drug Name	Indication	Type	Time under Consideration
X	X	Oncology	368
X	X	Non-Oncology	371
X	X	Non-Oncology	461
X	X	Oncology	519
X	X	Non-Oncology	1008

Fast Outliers (n=2)			
Drug Name	Indication	Type	Time under Consideration
X	X	Oncology	14
X	X	Non-Oncology	18

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CRaFT DRD Sub-Report: Note the current slide is for illustrative purposes and the same analysis is performed for **DRD** files in the DRD Sub-Report



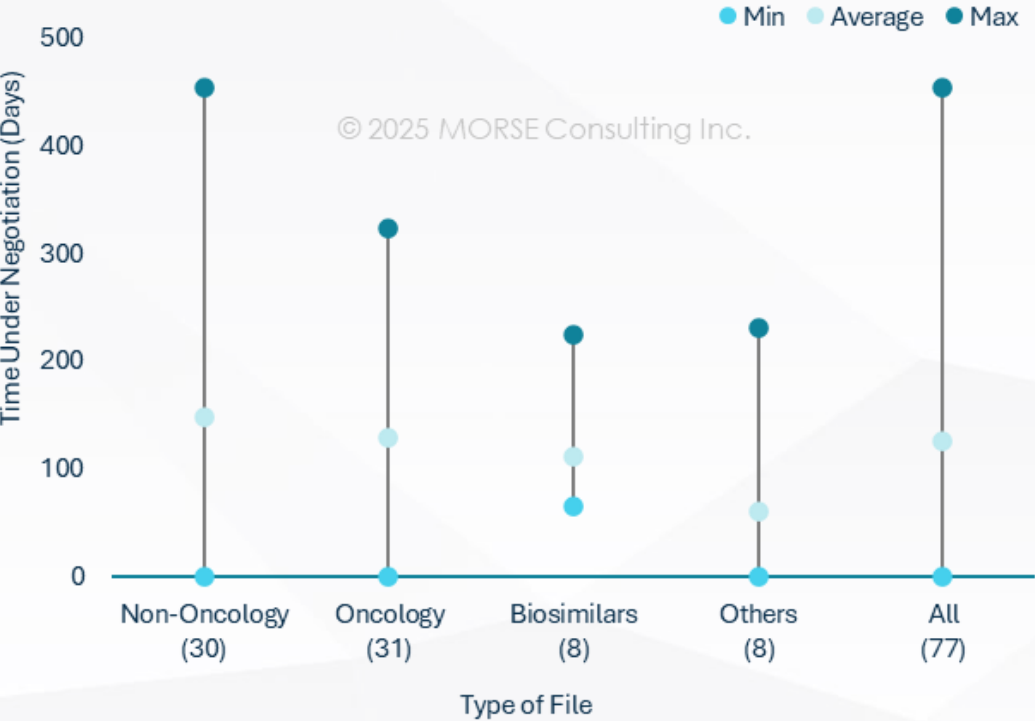
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pCPA COMPLETED WITH LOI: TIMELINE

By removing outliers, the average time under negotiation for Non-Oncology files decreased by x days, while for Oncology files it increased by x days, indicating there were more slow Non-Oncology outliers and more fast Oncology outliers.

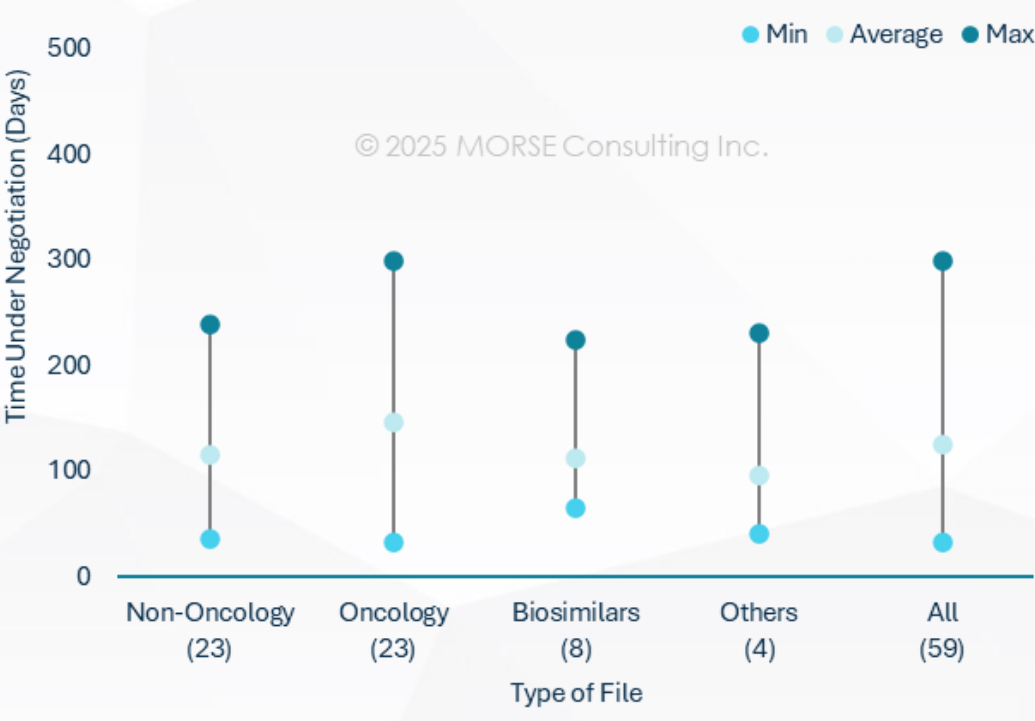
Time Under Negotiation For Files Completed In 2024

(Average, Max, Min; including outliers)



Time Under Negotiation For Files Completed In 2024

(Average, Max, Min; excluding outliers)



CRaFT Report: Note the current slide is for illustrative purposes. The same analysis is also performed for **pCPA Initiation** and **pCPA Closed** files, with outliers identified and payer insights included.

CRaFT DRD Sub-Report: Note the current slide is for illustrative purposes and the same analysis is performed for **DRD** files in the DRD Sub-Report

pCPA COMPLETED WITH LOI: TIMELINE OUTLIERS

X out of X Fast Outliers were initiated and completed in the same day, while the pattern amongst Slow Outliers is more nuanced.

Slow Outliers (n=X)			
Drug Name	Indication	Type	Time under Negotiation (days)
X	X	Oncology	304
X	X	Non-Oncology	307
X	X	Non-Oncology	321
X	X	Oncology	323
X	X	Non-Oncology	326
X	X	Non-Oncology	398
X	X	Non-Oncology	454

Fast Outliers (n=X)			
Drug Name	Indication	Type	Time under Negotiation (days)
X	X	Non-Oncology	0
X	X	Non-Oncology	0
X	X	Non-Oncology	0
X	X	Oncology	0
X	X	Oncology	0
X	X	Oncology	0
X	X	Oncology	0
X	X	Oncology	0
X	X	Other	0
X	X	Other	0
X	X	Other	3
X	X	Oncology	15

CRaFT Report: Note the current slide is for illustrative purposes. The same analysis is also performed for **pCPA Initiation** and **pCPA Closed** files, with outliers identified and payer insights included.

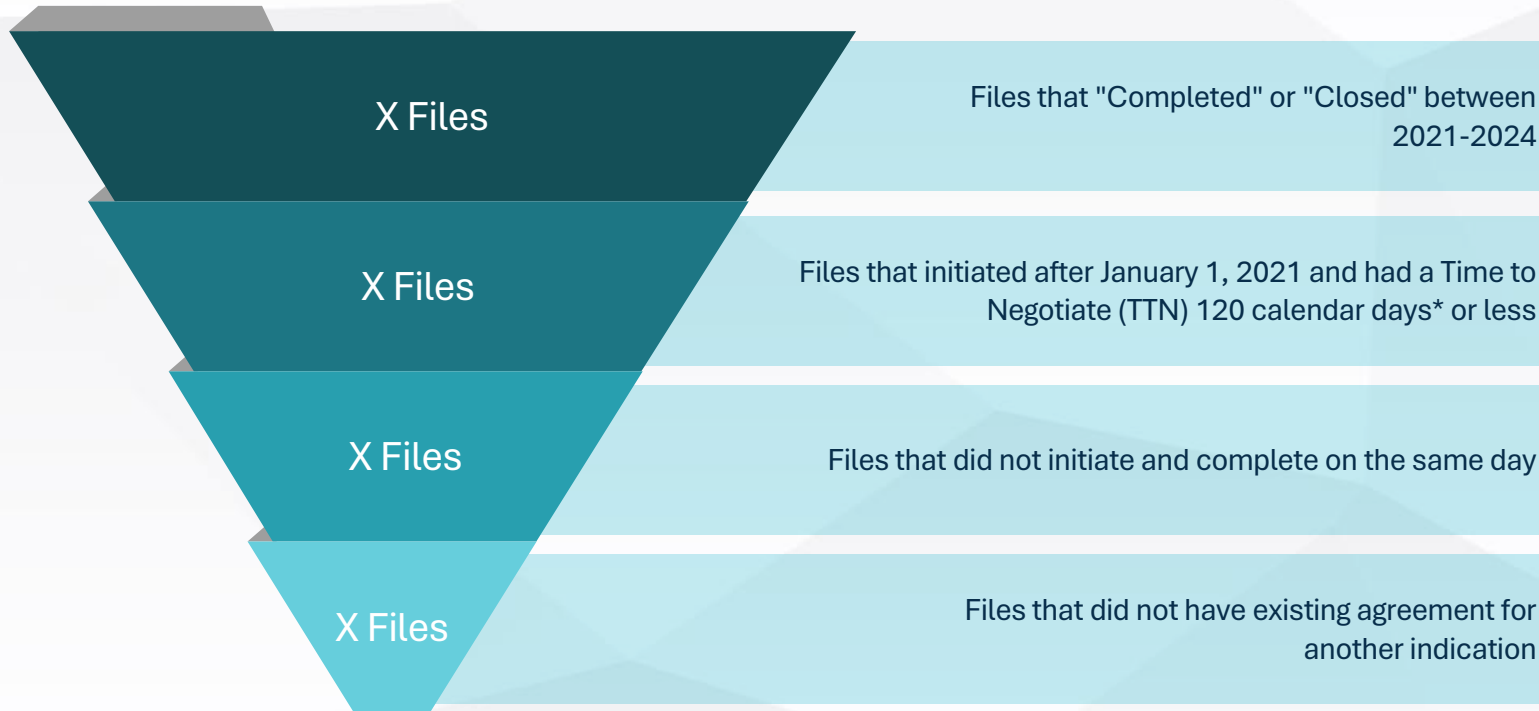
CRaFT DRD Sub-Report: Note the current slide is for illustrative purposes and the same analysis is performed for **DRD** files in the DRD Sub-Report



TARGETED NEGOTIATION PROCESS (TNP) ANALYSIS

As a result of pCPA's prioritization of brand negotiations, a backlog of files began to develop. In January 2021, the pCPA introduced the five step Targeted Negotiation Process (TNP) to address selected files.

MORSE METHODOLOGY:



LIMITATIONS:

- This analysis is purely speculative and there may be files included that did NOT go through TNP and conversely, files that did go through TNP that were not captured. Therefore, **these results are considered 'exploratory'** in nature.
- Certain files that met the methodology criteria were excluded based on MORSE's understanding of the TNP process.

CRaFT Report: Note the current slide is for illustrative purposes. The full report includes a list of the speculated TNP files, the timeline and volume of TNP vs. non-TNP files, TNP volume by year, as well as MORSE expert insights.

*120 days was chosen based on the following considerations:

- There is no public disclosure of which files have gone through TNP; thus MORSE developed an internal methodology to identify such files.
- The entire TNP requires 45 business days to complete, which translates into 63 calendar days;
- Holidays and special occasions might impact timelines and introduce certain delays.
- There is some flexibility in deadlines for response.

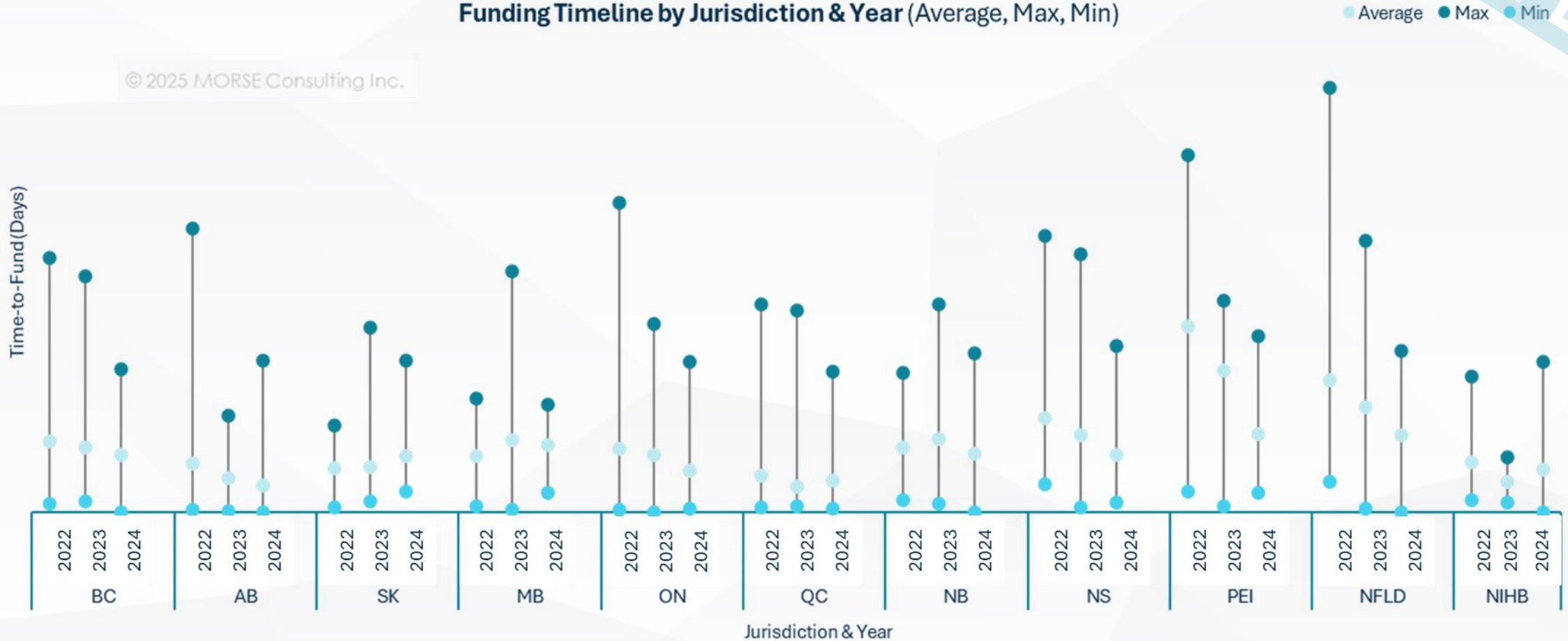


FUNDING TIMELINE BY JURISDICTION AND YEAR

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Funding Timeline by Jurisdiction & Year (Average, Max, Min)

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CRaFT DRD Sub-Report: Note the current slide is for illustrative purposes and the same analysis is performed for **DRD** files in the DRD Sub-Report

- Files that were funded but did not have a funding date were excluded from the timeline analysis.



HEALTH CANADA

CDA

p CPA

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Monthly Market Access Update

For CRaFT Subscribers

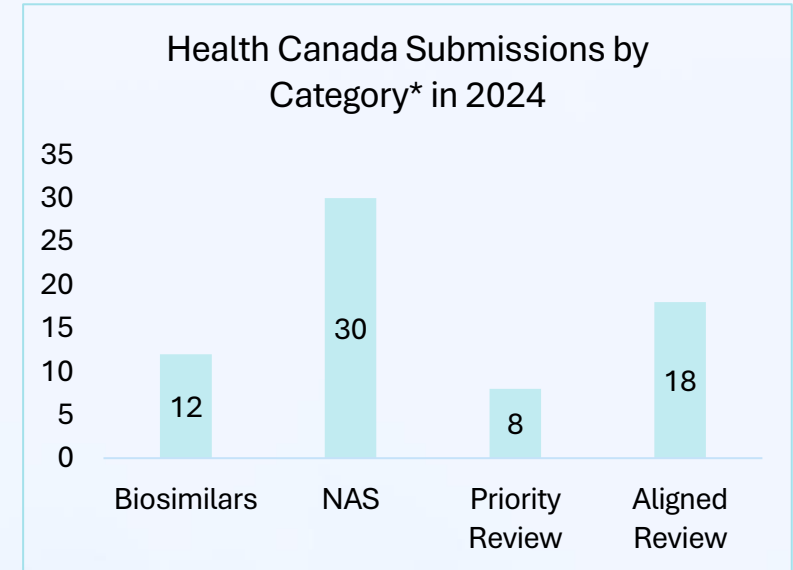
Included in the CRaFT 2025 Subscription

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September 2024 Edition

In September 2024, there were **4 new drug submissions** posted as under review by Health Canada

MEDICINAL INGREDIENT(S)	THERAPEUTIC AREA	SUBMISSION ACCEPTED	MANUFACTURER	SUBMISSION CLASS (IF APPLICABLE)
Inavolisib	Antineoplastic agents	2024-08-01	Hoffmann-la Roche Limited	<ul style="list-style-type: none"> New active substance Being reviewed under the Priority Review Policy Part of 'aligned review' with a health technology assessment organization
Melatonin	Psycheptics	2024-08-01	Neurim Pharmaceuticals Ltd.	<ul style="list-style-type: none"> Not applicable
Oritavancin diphosphate	Antibacterials for systemic use	2024-08-01	Xediton Pharmaceuticals Inc	<ul style="list-style-type: none"> New active substance Being reviewed under the Priority Review Policy
Quizartinib	Antineoplastic agents	2024-08-01	Daiichi Sankyo Pharma Canada Limited	<ul style="list-style-type: none"> New active substance Part of 'aligned review' with a health technology assessment organization



CDA posted* **6 final reimbursement recommendations** and **12 draft reimbursement recommendations** in September 2024.

18

**HTA reviews were posted
by CDA this month**

*6 Final Recommendations
12 Draft Recommendations*

1

**Files received a negative
'do not reimburse'
recommendations**

17

**Files received positive
'reimburse with
conditions'
recommendations**



SAMPLE

CDA posted 18 reimbursement reviews in September 2024*

REIMBURSEMENT REVIEWS						
DRUG NAME	INDICATION	MANUFACTURER	RECOMMENDATION	RECOMMENDATION DATE	TYPE	STAGE
Verzenio (abemaciclib)	Adjuvant treatment of HR-positive, HER2-negative early breast cancer	Eli Lilly Canada Inc.	Reimburse with Conditions	2024-08-23	Oncology	Draft
Tagrisso (osimertinib)	Non-small cell lung cancer	AstraZeneca Canada Inc.	Reimburse with Conditions	2024-08-26	Oncology	Draft
Keytruda (pembrolizumab)	Gastric or gastroesophageal junction (GEJ) adenocarcinoma	Merck Canada	Reimburse with Conditions	2024-08-27	Oncology	Draft
Tibsovo (ivosidenib)	Acute myeloid leukemia (AML)	Servier Canada Inc.	Reimburse with Conditions	2024-08-28	Oncology	Draft
Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor)	Cystic fibrosis, F508del or responsive CFTR mutation, 2 years and older	Vertex Pharmaceuticals	Reimburse with Conditions	2024-09-10	Non-oncology	Draft
Voydeya (danicopan)	Paroxysmal nocturnal hemoglobinuria (PNH)	Alexion Pharma	Reimburse with Conditions	2024-09-11	Non-oncology	Draft
Cabtreo (clindamycin plus benzoyl peroxide and adapalene)	Acne vulgaris	Bausch Health	Reimburse with Conditions	2024-09-11	Non-oncology	Draft
Winrevair (sotatercept)	Pulmonary arterial hypertension (WHO group 1)	Merck Canada	Reimburse with Conditions	2024-09-12	Non-oncology	Draft
Wainua (eplontersen)	Polyneuropathy in hereditary transthyretin-mediated amyloidosis	AstraZeneca Canada	Reimburse with Conditions	2024-09-12	Non-oncology	Draft

*The month a recommendation is posted refers to the month it is posted on the CDA website. The Recommendation Date for draft recommendations refers to the date the draft recommendation was posted for stakeholder feedback; for final recommendations it refers to the date the final recommendation was issued to sponsor and drug plans.



SAMPLE

CDA posted 18 reimbursement reviews in September 2024* (Cont'd)

REIMBURSEMENT REVIEWS						
DRUG NAME	INDICATION	MANUFACTURER	RECOMMENDATION	RECOMMENDATION DATE	TYPE	STAGE
Alecensaro (alectinib)	ALK-positive NSCLC	Hoffmann-La Roche	Reimburse with Conditions	2024-09-23	Oncology	Draft
Carvykti (ciltacabtagene autoleucel)	Relapsed or refractory multiple myeloma	Janssen Inc	Reimburse with Conditions	2024-09-24	Oncology	Draft
Ayvakyt (avapritinib)	Advanced Systemic Mastocytosis	Medison Pharma	Reimburse with Conditions	2024-09-25	Oncology	Draft
Adcetris (Brentuximab vedotin)	Hodgkin lymphoma	Seagen Canada	Reimburse with Conditions	2024-08-29	Oncology	Final
Truqap (capivasertib)	HR-positive, HER2-negative locally advanced or metastatic breast cancer	AstraZeneca Canada	Reimburse with Conditions	2024-08-30	Oncology	Final
Cosentyx (secukinumab)	Hidradenitis suppurativa	Novartis Canada	Reimburse with Conditions	2024-09-12	Non-oncology	Final
Olumiant (baricitinib)	Alopecia areata, severe	Eli Lilly Canada	Reimburse with Conditions	2024-09-13	Non-oncology	Final
N/A (Nab-paclitaxel)	Adjuvant treatment of pancreatic cancer	N/A	Reimburse with Conditions	2024-09-26	Non-sponsored	Final
N/A (Nab-paclitaxel)	Previously treated advanced (locally advanced unresectable or metastatic) pancreatic cancer	N/A	Do Not Reimburse	2024-09-26	Non-sponsored	Final



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CDA released **1 provisional funding algorithm** in September 2024

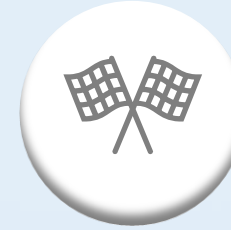
PROVISIONAL FUNDING ALGORITHM		
DRUG(S) AND/OR THERAPEUTIC AREA	STAGE	SUBMIT FEEDBACK BY DATE
<u>Adult Classical Hodgkin Lymphoma</u>	Feedback on draft report — OPEN	2024-09-26



SAMPLE



6 new files are under Active
Negotiation



4 files Concluded with an LOI



0 files Concluded without an
agreement



pCPA decided to not pursue
negotiations for **2 files**



In September, there were **6 new files under active negotiation** with the pCPA.

FILES UNDER ACTIVE NEGOTIATION					
DRUG NAME	INDICATION	MANUFACTURER	PRODUCT TYPE	ENGAGEMENT DATE	TTI*
Evkeeza (evinacumab)	Homozygous familial hypercholesterolemia (HoFH)	Ultragenyx Pharmaceutical	Non-oncology	2024-09-04	236
Remsima (infliximab)	Ulcerative Colitis	Celltrion Healthcare Co	Non-oncology	2024-09-06	137
Remsima (infliximab)	Crohns disease	Celltrion Healthcare Co	Non-oncology	2024-09-06	137
Awiqli (insulin icodec)	Diabetes mellitus, type 2	Novo Nordisk Canada Inc.	Non-oncology	2024-09-12	118
Bimzelx (bimekizumab)	Ankylosing spondylitis	UCB Canada	Non-oncology	2024-09-20	127
Bimzelx (bimekizumab)	Psoriatic arthritis	UCB Canada	Non-oncology	2024-09-20	128



In September, **4 files successfully concluded negotiations** with an LOI.

FILES THAT CONCLUDED WITH AN LOI

DRUG NAME	Manufacturer	Indication	PRODUCT TYPE	ENGAGEMENT DATE	PROCESS CONCLUSION DATE	TTI*	TTN**
Yescarta (axicabtagene ciloleucel)	Diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma (HGBL) Gilead Sciences Canada Inc.	Oncology	Completed	2023-09-26	2024-09-06	235 days	346 days
Slynd (drospirenone)	Contraceptive, oral Duchesnay Inc	Non-oncology	Completed	2024-08-20	2024-09-11	155 days	22 days
Orladeyo (berotralstat)	hereditary angioedema (HAE) BioCryst Pharmaceuticals Inc.	Non-oncology	Completed	2024-01-31	2024-09-12	329 days	225 days
Qulipta (atogepant)	Migraine, prevention AbbVie Corporation	Non-oncology	Completed	2024-08-09	2024-09-25	25 days	47 days

MORSE Insights

- Slynd, an oral contraceptive, completed negotiation in 22 days. CDA analysis of the Slynd BIA found that it should have no increase to drug plans budgets based on its submitted price relative to the published list price of norethindrone.
- Qulipta for migraine prevention completed negotiation in 47 days. It was previously negotiated with LOI for episodic migraine under similarly quick timelines.
- pCPA completed an LOI for Yescarta, a CAR T-cell therapy, after almost 1 year of negotiation.



In September, no negotiations were **closed without an LOI**. pCPA **did not pursue negotiation for 2 files**.

FILES THAT WERE NOT NEGOTIATED							
DRUG NAME	INDICATION	MANUFACTURER	PRODUCT TYPE	RECOMMENDATION DATE	RECOMMENDATION TYPE	pCPA DECISION DATE	TIME TO DECISION
Rybrevant (Amivantamab)	Non-Small Cell Lung Cancer (NSCLC)	Janssen Inc.	Other	NA		2024-09-19	NA
Sogroya (somapacitan)	Growth Hormone Deficiency (GHD)	Novo Nordisk Canada Inc.	Non-oncology	2023-11-17	Reimburse with clinical criteria and/or conditions	2024-09-26	314 days

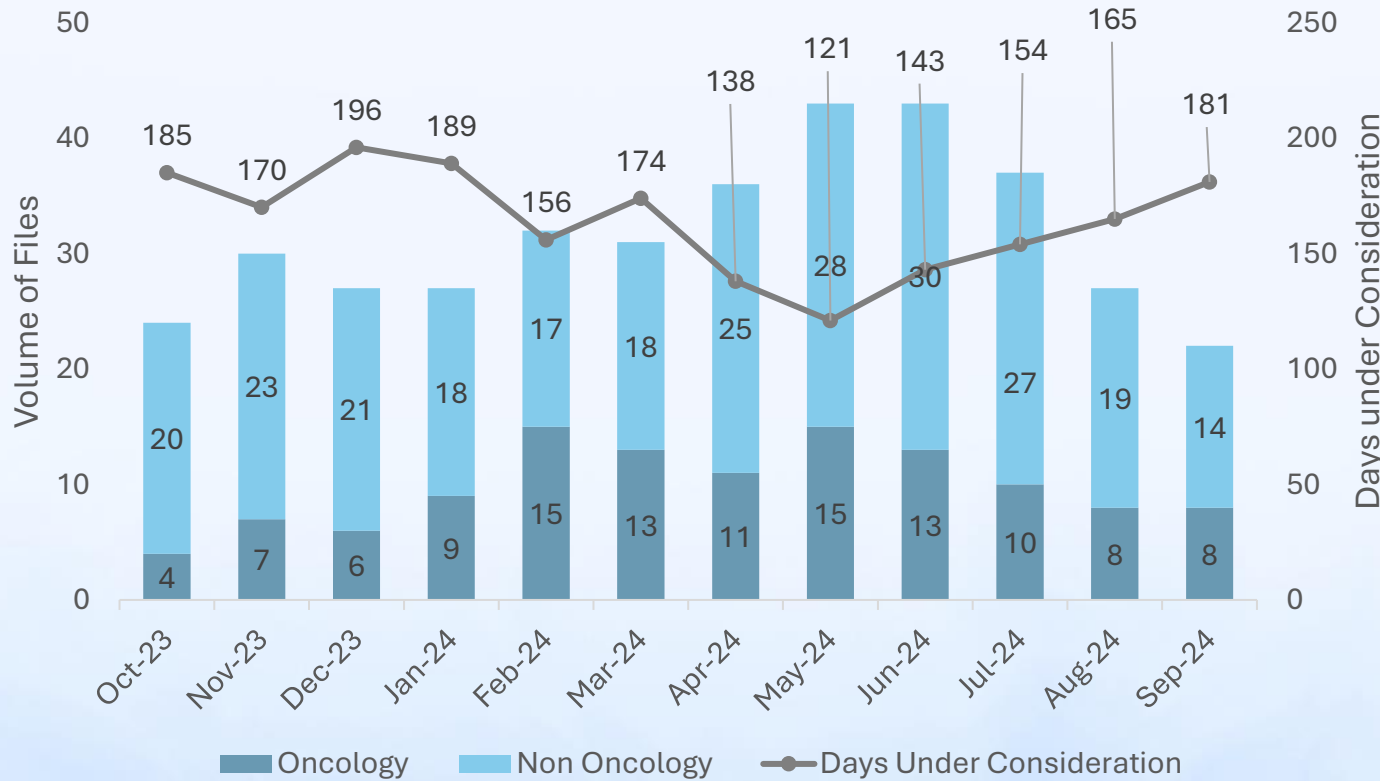
MORSE Insights

- pCPA declined to negotiate Sogroya almost a year after its CDA recommendation of ‘Reimburse with conditions’. The recommendation conditions included that it should be negotiated to cost no more than the least costly reimbursed somatropin, and for the feasibility of adoption to be addressed. INESSS did not recognize therapeutic value of the product.
- pCPA also declined to negotiate Rybrevant, but has not indicated an associated CDA recommendation. It is highly unusual for pCPA to post a declined negotiation without an associated HTA recommendation.
- A public drug plan-initiated review of Nab-paclitaxel for previously treated advanced (locally advanced unresectable or metastatic) pancreatic cancer in combination with gemcitabine received a ‘Do not reimburse’ from FMEC due to evidence uncertainty and potential harms. This is the first negative recommendation to come from FMEC.



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Volume of Files (left axis) and Average Time (right axis) Under Consideration as of Month End



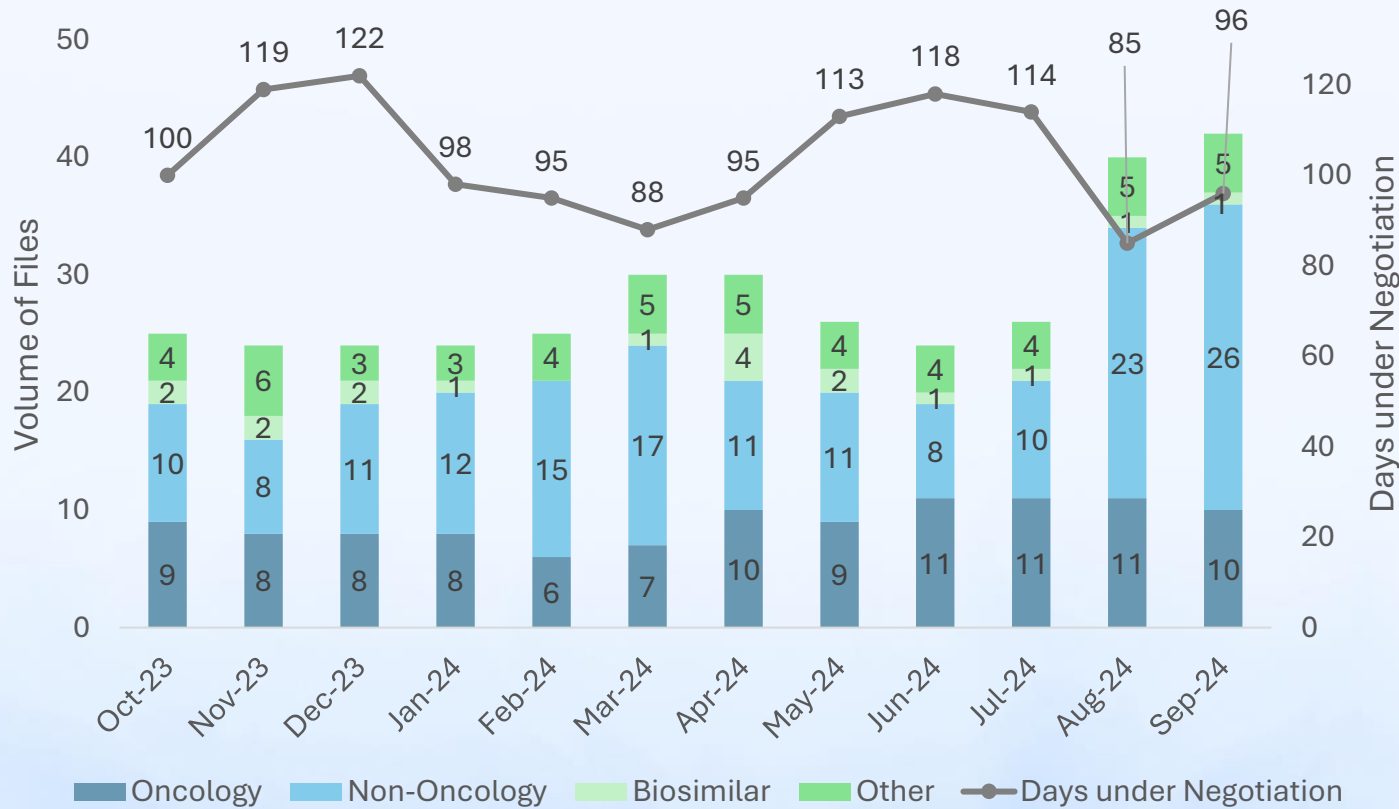
MORSE Insights

- In September, the CDA issued final recommendations for two non-oncology files. Meanwhile, the pCPA initiated six files and declined one file linked to a CDA recommendation, all non-oncology, reducing the total volume under consideration to 22 files. This marks the lowest volume under consideration in the past year.
- The average days under consideration for files yet to be initiated increased to 181 days driven predominantly by 7 files being under consideration for longer than 6 months.



SAMPLE

Volume (left axis) and Average Duration (right axis) of Active Negotiation as of Month End



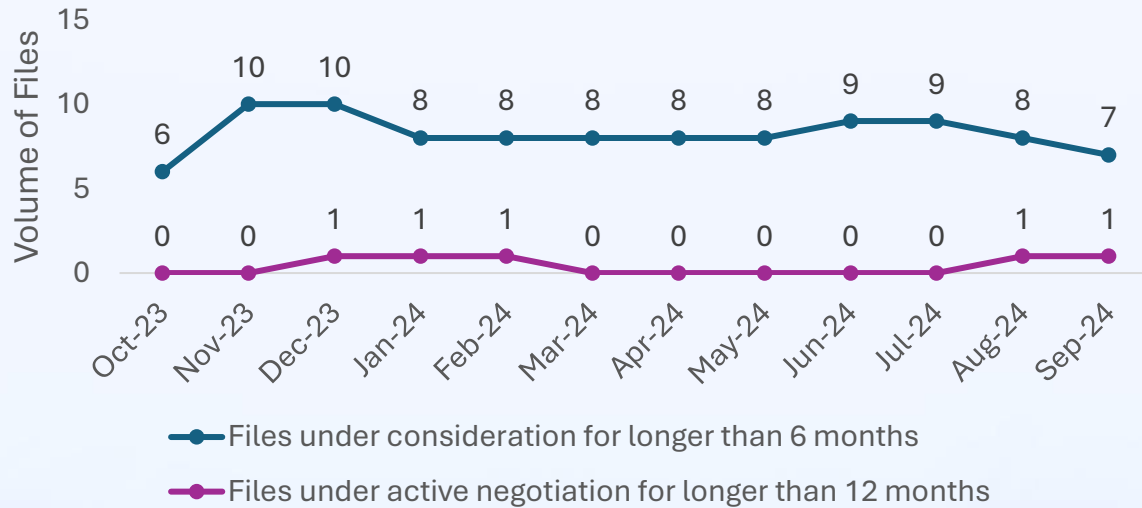
MORSE Insights

- pCPA completed negotiations for 1 oncology and 3 non-oncology files in September, while initiating negotiations for 6 non-oncology files, bringing the number of files under active negotiation to 42, the highest number in the past 12 months.
- The majority of files under active negotiation are non-oncology products (26), with over 2.5 times the volume as are active in oncology.
- The average time under negotiation for active files increased from the previous month to 96 days, still below the annual average of 104 days. One long-term negotiation (Yescarta, 346 days) and two quick negotiations (Slynd, 22 days; Qulipta, 47 days) completed with LOIs.

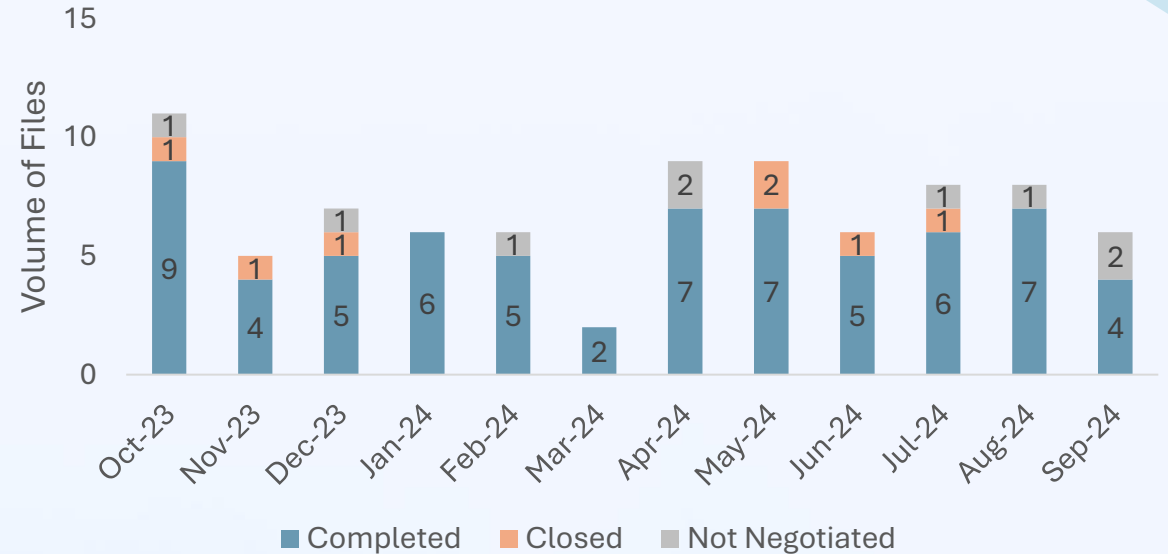


SAMPLE

Files under Consideration \geq 6 Months & Under Active Negotiation \geq 12 Months



Files Adjudicated by the pCPA by Month



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- pCPA initiated Evkeeza in September, which had been under consideration for more than 6 months, reducing the number of long-term under-consideration files by one.
- 3 of the 7 remaining long-term under-consideration files had negative CDA recommendations.
- One file remains under active negotiation for over a year: Pluvicto indicated for metastatic castration-resistant prostate cancer was engaged in August 2023.
- pCPA completed negotiation for 4 files in September, the lowest volume in the past 6 months.





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