Subsequent Submissions in Canadian Market Access

Trends, Timelines, and Outcomes

CDA-AMC Symposium 2026

Presenter: Lana Duan, *Senior Manager, MORSE Consulting*

MORSE CONSULTING | DECIPHERING MARKET ACCESS

Presenter

Lana Duan, MSc

Senior Manager in Market Access & Data Analytics
MORSE Consulting Inc.

Lana holds an MSc in medical science from the University of Toronto and has 6+ years of experience in pharmaceutical market access consulting. She has a profound understanding of administrative health databases, RWE, HTA, pCPA, payers, and PMPRB. Her expertise lies in using data-driven insights to inform strategic decision-making within the healthcare space.

MORSE Consulting Inc. is Canada's leading market access strategy consultancy, focused on developing comprehensive reimbursement strategies that address our clients' needs. MORSE is known for its credibility and unique insights and expertise with a team of reputable experts in health technology assessment (HTA), health economics, the pan-Canadian Pharmaceutical Alliance (pCPA), and numerous ex-public and ex-private payers.

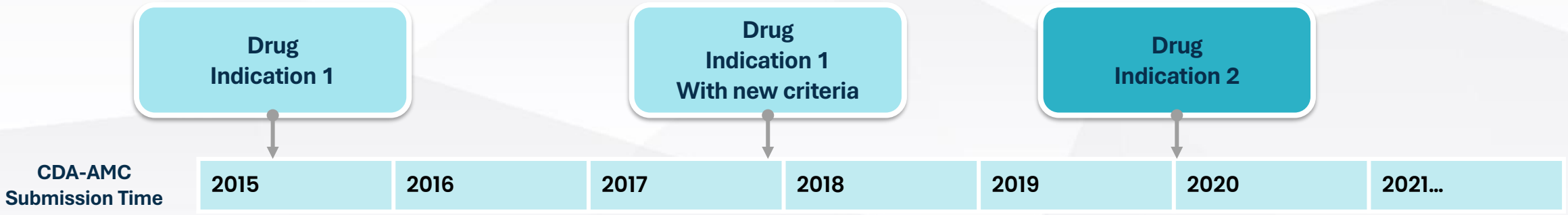
Background

As drug development increasingly targets specific populations and evolving treatment paradigms, understanding market access for therapies with expanding clinical criteria and/or new indications is critical.

We speculated that:

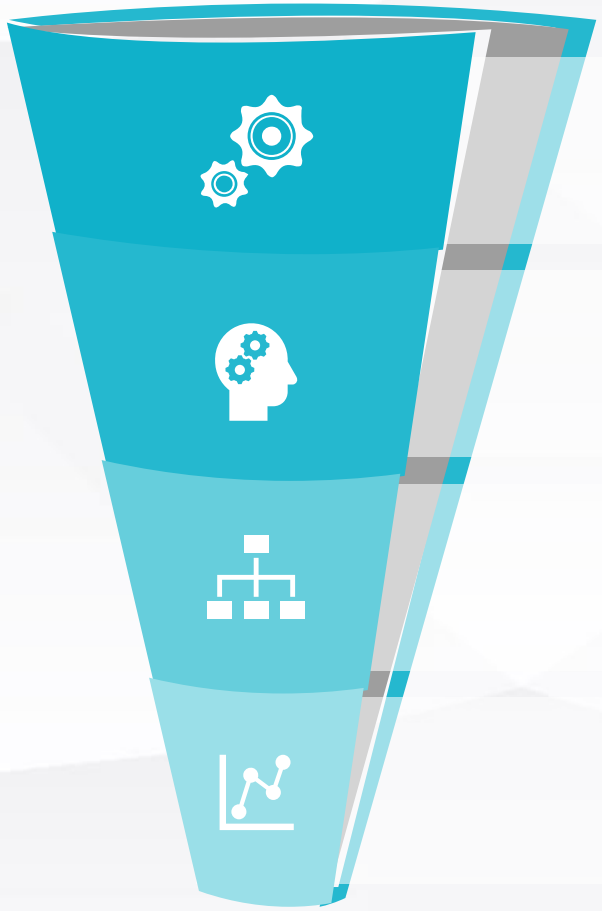
CDA-AMC Reviews: Prior CDA-AMC reviews do not guarantee success for subsequent submissions for the same drug, as robust clinical and economic evidence is the key determinant for HTA success.

pCPA Negotiation & Jurisdictional Listing: Subsequent submissions for the same product can have higher success rate and accelerated timelines for pCPA negotiation and jurisdictional listing, likely due to prior negotiations and existing LOIs and listings, which may reduce negotiation complexity and implementation challenges for subsequent reviews.



Methodology

We focused on non-oncology drugs and compared rate of success as well as negotiation and listing timelines for new drug submissions, new indication submissions, and criteria change submissions.



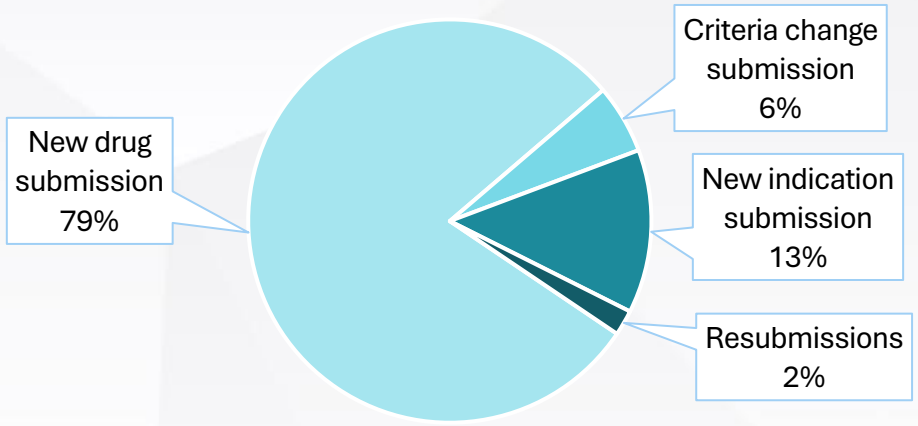
1. **Inclusion Criteria:** Non-oncology drugs with final CDA-AMC recommendations between January 1, 2015 and December 31, 2025, excluding non-sponsored and request for advice reviews.
2. **Categorization:** Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication).
3. **Criteria change submissions:** Two reviewers categorized criteria change submissions into subcategories including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)
4. **Analysis:** The volumes, outcomes, and timelines across CDA-AMC, pCPA, and jurisdictional listing were analyzed and compared.

Findings

There have been 23 criteria change submissions and 46 new indication submissions in the past 10 years.

N=409

Non-Oncology files that received a final recommendation from CDA-AMC between 2015-01-01 and 2025-12-31



N=330 (79%)
New drug submissions

Drugs submitted to CDA-AMC for the first time in the study timeframe

N=23 (6%)
Criteria change submissions

Drugs submitted to CDA-AMC for criteria change, including age group expansion, initiation criteria change, formulation change, etc.

N=46 (13%)
New indication submissions

Drugs submitted to CDA-AMC for a new indication, with at least one prior recommendation issued for another indication

N=10 (2%)
Resubmissions

Drugs re-submitted to CDA-AMC due to an initial negative recommendation

Data Sources:

- CDA-AMC Reimbursement Reviews.
- MORSE Consulting Data Intelligence Tool.

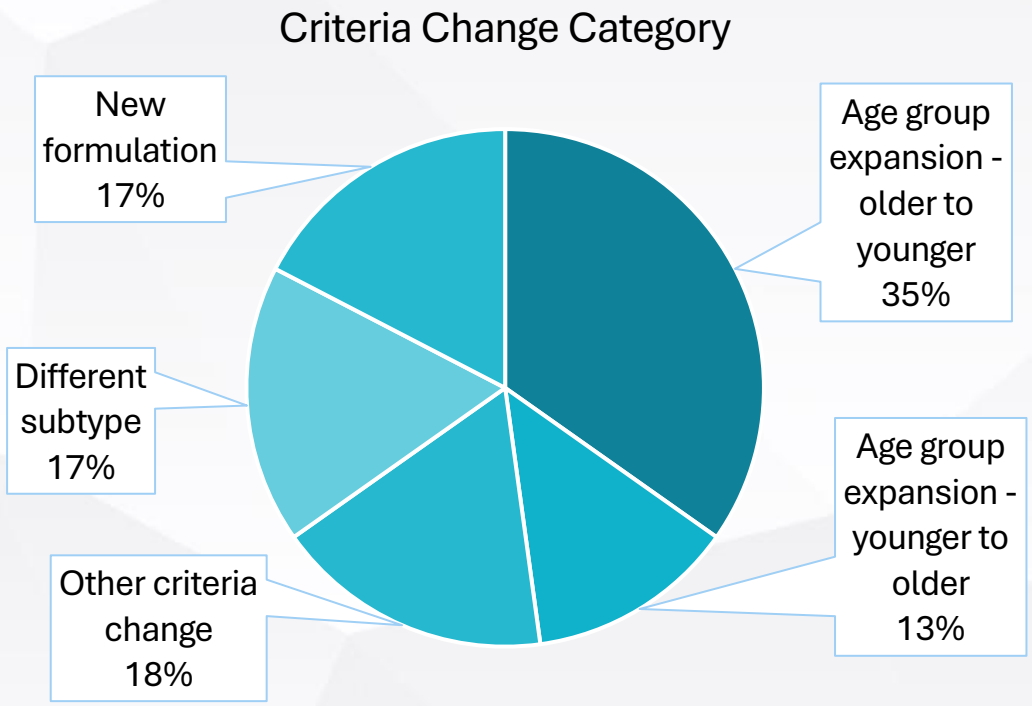
Methodology:

- Results includes all non-oncology files that received a final recommendation between 2015-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)

Findings

Close to 50% of criteria change submissions were age group expansions, with more submitting for expansion to younger population.

Criteria Change Category	Number of Files
Age group expansion - older population to younger	8
Age group expansion - younger population to older	3
Different subtype (e.g., episodic and chronic migraine)	4
New formulation (e.g., Intravenous/IV to Subcutaneous/SC)	4
Other criteria change (e.g., initiation criteria change)	4



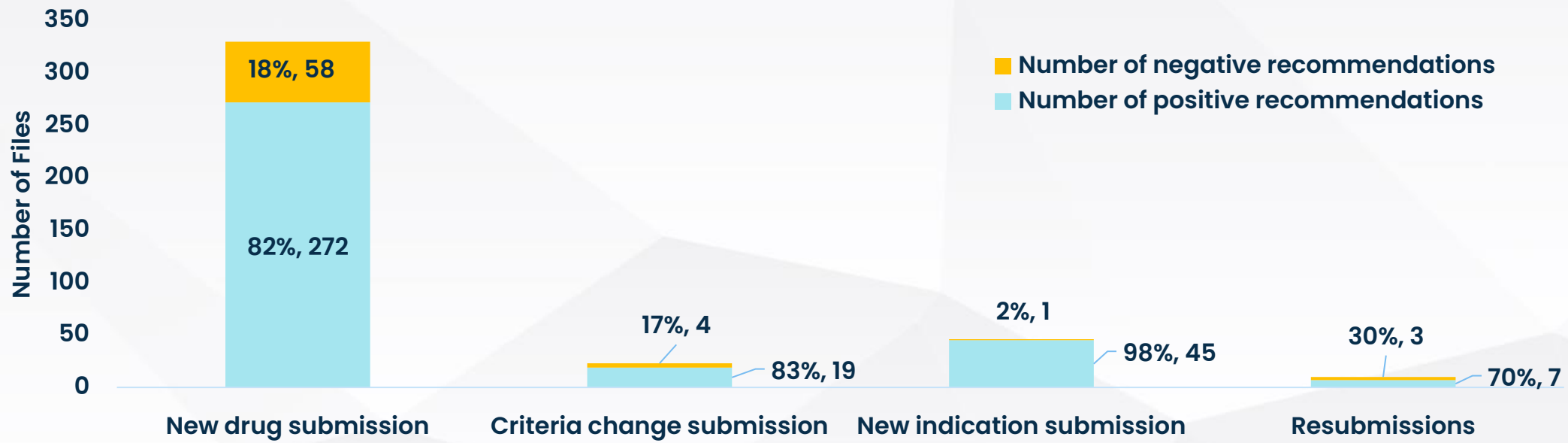
Data Sources:
- CDA-AMC Reimbursement Reviews.
- MORSE Consulting Data Intelligence Tool.

Methodology:
- Results includes all non-oncology files that received a final recommendation between 2015-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)

Findings

Drugs submitted for new indications (with prior reviews) had a higher percentage of positive recommendation (98%) than drugs submitted to CDA-AMC for the first time (82%) or submissions for criteria change (83%).

Number of CDA-AMC positive/negative recommendation by submission type



Data Sources:

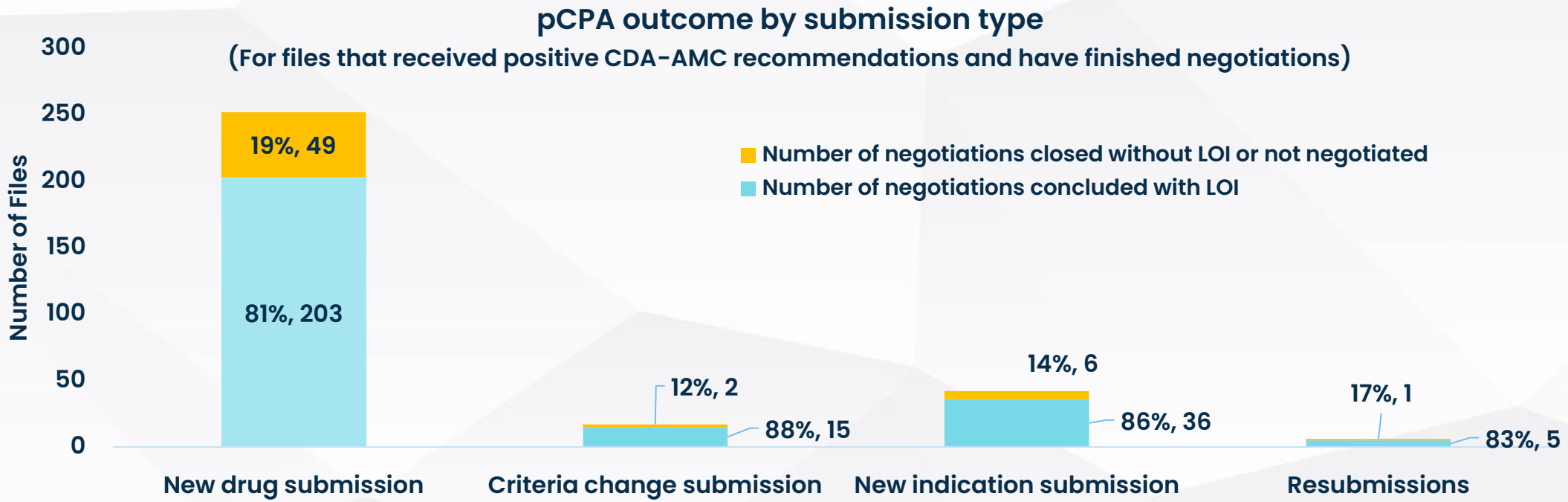
- CDA-AMC Reimbursement Reviews.
- MORSE Consulting Data Intelligence Tool.

Methodology:

- Results includes all non-oncology files that received a final recommendation between 2015-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded.
- CDA-AMC positive recommendations include 'Reimburse/List', 'Reimburse/List with Conditions', and 'Time-Limited Reimbursement'; CDA-AMC negative recommendations include 'Do not List/Reimburse' recommendations.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)
- New drug submissions: Drugs submitted to CDA-AMC for the first time.
- Criteria change submissions: Drugs submitted to CDA-AMC for criteria change, including age group expansion, initiation criteria change, formulation change, etc.
- New indication submissions: Drugs submitted to CDA-AMC for a new indication, with at least one prior recommendation issued for another indication

Findings

Drugs submitted for new indications (86%) and criteria change (88%) had slightly higher percentage of successful pCPA negotiations than drugs submitted for the first time (81%).



Data Sources:

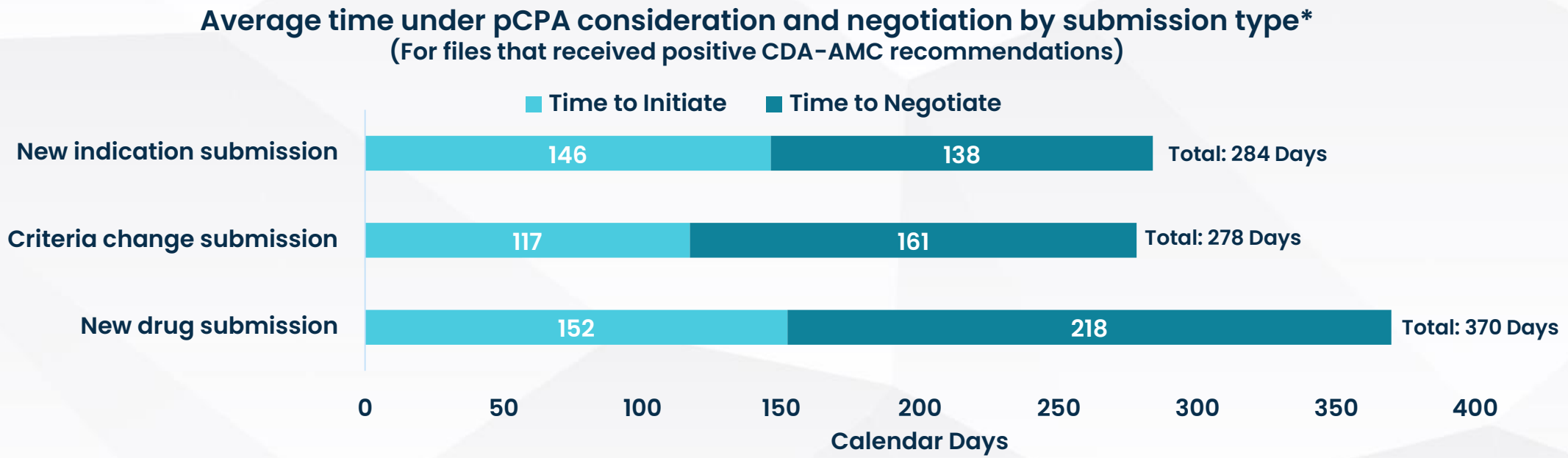
- CDA-AMC Reimbursement Reviews.
- Brand Name Drug Negotiations Status | pCPA
- MORSE Consulting Data Intelligence Tool.

Methodology:

- Results includes non-oncology files that received a positive final recommendation between 2015-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded. Files under consideration, under active negotiation or not negotiated have been excluded.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)
- New drug submissions: Drugs submitted to CDA-AMC for the first time.
- Criteria change submissions: Drugs submitted to CDA-AMC for criteria change, including age group expansion, initiation criteria change, formulation change, etc.
- New indication submissions: Drugs submitted to CDA-AMC for a new indication, with at least one prior recommendation issued for another indication

Findings

Drugs submitted for new indication (284 days) and criteria expansion (278 days) had faster negotiation timelines than drugs submitted for the first time (370 days).



*Note that timeline analysis was not done for resubmission files as the sample size was smaller than 10.

Data Sources:

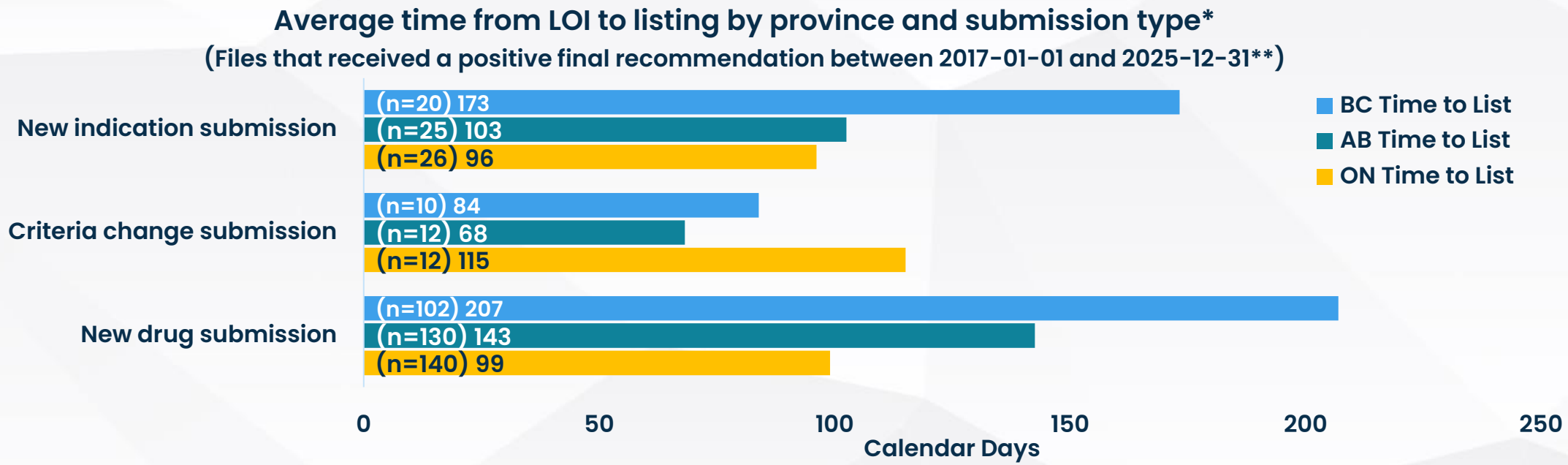
- CDA-AMC Reimbursement Reviews.
- Brand Name Drug Negotiations Status | pCPA
- MORSE Consulting Data Intelligence Tool.

Methodology:

- Results includes non-oncology files that received a positive final recommendation between 2015-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded. Files under consideration, under active negotiation or not negotiated have been excluded.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)
- Time to initiate: The average time between CDA-AMC final recommendation and pCPA negotiation initiation; Time to negotiate: The average time between pCPA negotiation initiation and pCPA negotiation conclusion.
- New drug submissions: Drugs submitted to CDA-AMC for the first time.
- Criteria change submissions: Drugs submitted to CDA-AMC for criteria change, including age group expansion, initiation criteria change, formulation change, etc.
- New indication submissions: Drugs submitted to CDA-AMC for a new indication, with at least one prior recommendation issued for another indication

Findings

Drugs submitted for criteria change and new indications had faster time to list in BC and AB after LOI than drugs submitted for the first time.



*Note that timeline analysis was not done for resubmission files as the sample size was smaller than 10.
**Note that listing data is available for files that received a positive final recommendation between 2017-01-01 and 2025-12-31, as of 2026-02-01.

Data Sources:

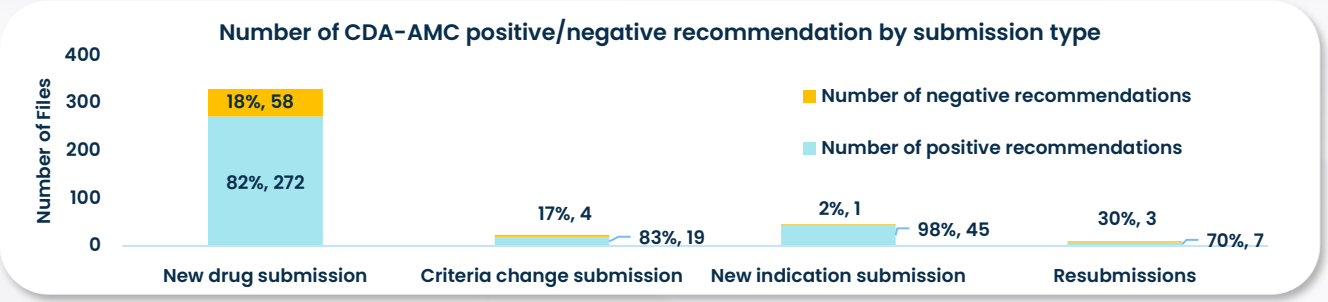
- CDA-AMC Reimbursement Reviews.
- Ontario Formulary Search; British Columbia PharmaCare Drug Review Results; Alberta DBL Table of Contents | Alberta.ca.
- MORSE Consulting Data Intelligence Tool.

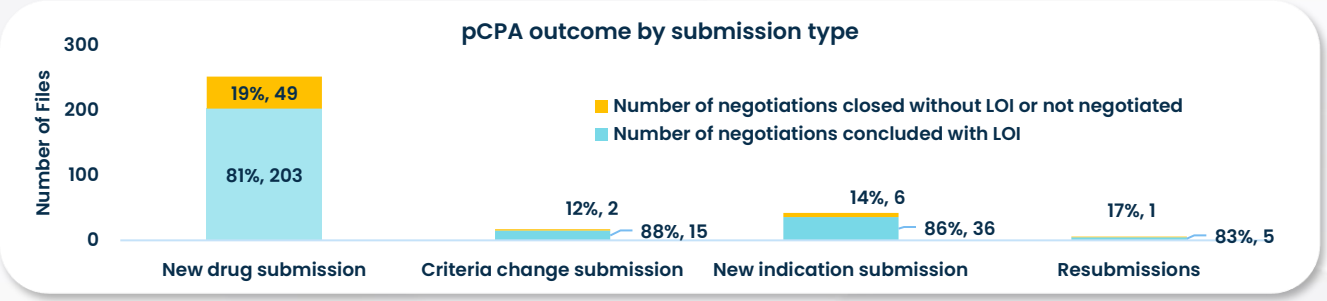
Methodology:

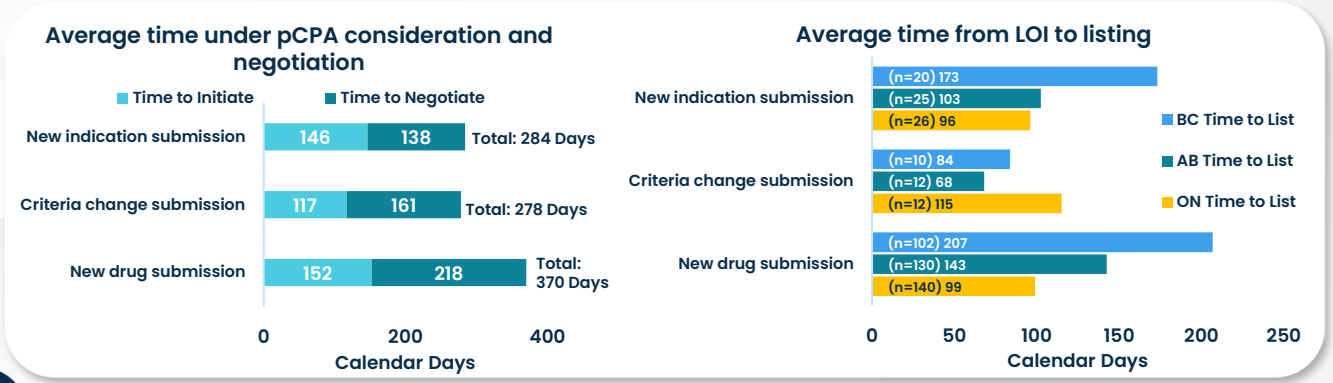
- Results includes non-oncology files that received a positive final recommendation between 2017-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)
- BC: British Columbia; AB: Alberta; ON: Ontario; Time to list: the average time between pCPA conclusion with LOI date and listing date.
- New drug submissions: Drugs submitted to CDA-AMC for the first time.
- Criteria change submissions: Drugs submitted to CDA-AMC for criteria change, including age group expansion, initiation criteria change, formulation change, etc.
- New indication submissions: Drugs submitted to CDA-AMC for a new indication, with at least one prior recommendation issued for another indication

Summary of Findings

New indication submissions had higher rate of positive CDA-AMC reviews than new drug submissions, and both criteria change and new indication submissions had faster pCPA and listing timelines.







Summary of Findings

- Among the 23 criteria change submissions, close to half were associated with age group expansion, with 2/3 expanding from older to younger population.
- Prior CDA-AMC reviews do not ensure success for subsequent submission, but new indication submissions showed higher success rates, and both criteria change and new indication submissions showed faster downstream timelines at pCPA and jurisdictional listing.
- Existing negotiations, agreements, and system familiarity likely contribute to more efficient pCPA negotiations and provincial implementation for subsequent submissions.

Methodology & Limitations

- Non-oncology drugs with final CDA-AMC recommendations between January 1, 2015 and December 31, 2025, excluding non-sponsored and request for advice reviews.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication).
- Two reviewers categorized criteria change submissions into subcategories including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)

Data Sources:

- CDA-AMC Reimbursement Reviews. Brand Name Drug Negotiations Status | pCPA. Ontario Formulary Search; British Columbia PharmaCare Drug Review Results; Alberta DBL Table of Contents | Alberta.ca.
- MORSE Consulting Data Intelligence Tool.

Appendix

Files that submitted for criteria change and their corresponding prior submission

Brand Name	Generic Name	CDA-AMC Recommendation	CDA-AMC Recommendation Date	CDA Link	Indication	Reason for Subsequent Submission
Adtralza	tralokinumab	Negative	2022-03-07	https://www.cda-amc.ca/tralokinumab	Atopic dermatitis	First
Adtralza	tralokinumab	Negative	2024-05-08	https://www.cda-amc.ca/tralokinumab-0	Atopic dermatitis	Age group expansion - older to younger; Initial negative
Crysvita	burosumab	Positive	2020-05-27	https://www.cda-amc.ca/burosumab	X-linked hypophosphatemia	First
Crysvita	burosumab	Positive	2024-10-10	https://www.cda-amc.ca/burosumab-0	X-linked hypophosphatemia	Age group expansion - younger to older; reassessment
Dupixent	dupilumab	Positive	2021-06-08	https://www.cda-amc.ca/dupilumab-1	Asthma	First
Dupixent	dupilumab	Positive	2023-01-20	https://www.cda-amc.ca/dupilumab-3	Asthma	Age group expansion - older to younger
Dupixent	dupilumab	Negative	2018-06-27	https://www.cda-amc.ca/dupilumab	Atopic dermatitis	First
Dupixent	dupilumab	Positive	2020-04-22	https://www.cda-amc.ca/dupilumab-0	Atopic dermatitis	Age group expansion - older to younger; Initial negative
Dupixent	dupilumab	Positive	2023-10-13	https://www.cda-amc.ca/dupilumab-5	Atopic dermatitis	Age group expansion - older to younger
Entresto	sacubitril/valsartan	Positive	2016-03-18	https://www.cda-amc.ca/sacubitrilvalsartan	Heart failure	First
Entresto	sacubitril/valsartan	Positive	2021-03-24	https://www.cda-amc.ca/sacubitrilvalsartan-0	Heart failure	Criteria change - reassessment
Entyvio	vedolizumab	Positive	2016-10-31	https://www.cda-amc.ca/vedolizumab-0	Crohn's disease	First
Entyvio	vedolizumab	Positive	2021-01-19	https://www.cda-amc.ca/vedolizumab-2	Crohn's disease	Formulation change (IV to SC)
Entyvio	vedolizumab	Positive	2015-10-28	https://www.cda-amc.ca/vedolizumab	Ulcerative colitis	First
Entyvio	vedolizumab	Positive	2020-05-19	https://www.cda-amc.ca/vedolizumab-1	Ulcerative colitis	Formulation change (IV to SC)

Data Sources:

- CDA-AMC Reimbursement Reviews.
- MORSE Consulting Data Intelligence Tool.

Methodology:

- Results includes all non-oncology files that received a final recommendation between 2015-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)

Appendix

Files that submitted for criteria change and their corresponding prior submission

Brand Name	Generic Name	CDA-AMC Recommendation	CDA-AMC Recommendation Date	CDA Link	Indication	Reason for Subsequent Submission
Eylea	aflibercept	Positive	2015-05-07	https://www.cda-amc.ca/aflibercept-0	Diabetic macular edema	First
Eylea HD	aflibercept 8mg/0.07ml	Positive	2024-06-05	https://www.cda-amc.ca/aflibercept-8mg007ml-0	Diabetic macular edema	Formulation change (low dose to high dose)
Ferriprox	deferiprone	Positive	2016-03-18	https://www.cda-amc.ca/deferiprone	Iron overload	First
Ferriprox	deferiprone	Positive	2023-01-19	https://www.cda-amc.ca/deferiprone-0	Iron overload	Different subtype
Forxiga	dapagliflozin	Positive	2015-11-20	https://www.cda-amc.ca/dapagliflozin	Type 2 diabetes mellitus	First
Forxiga	dapagliflozin	Negative	2016-04-27	https://www.cda-amc.ca/dapagliflozin-0	Type 2 diabetes mellitus	Criteria change - monotherapy to combo
Jardiance	empagliflozin	Positive	2015-10-15	https://www.cda-amc.ca/empagliflozin	Type 2 diabetes mellitus	First
Jardiance	empagliflozin	Positive	2016-10-26	https://www.cda-amc.ca/empagliflozin-0	Type 2 diabetes mellitus	Different subtype
Jorveza	budesonide	Positive	2020-10-28	https://www.cda-amc.ca/budesonide-0	Eosinophilic esophagitis	First
Jorveza	budesonide	Positive	2021-08-05	https://www.cda-amc.ca/budesonide-1	Eosinophilic esophagitis	Criteria change – induction only to maintenance
Orkambi	lumacaftor/ivacaftor	Negative	2016-10-26	https://www.cda-amc.ca/lumacaftorivacaftor	Cystic fibrosis	First
Orkambi	lumacaftor/ivacaftor	Negative	2018-09-26	https://www.cda-amc.ca/lumacaftorivacaftor-0	Cystic fibrosis	Age group expansion - older to younger; initial negative
Qulipta	atogepant	Positive	2023-06-14	https://www.cda-amc.ca/atogepant	Migraine	First
Qulipta	atogepant	Positive	2024-07-15	https://www.cda-amc.ca/atogepant-0	Migraine	Different subtype

Data Sources:

- CDA-AMC Reimbursement Reviews.
- MORSE Consulting Data Intelligence Tool.

Methodology:

- Results includes all non-oncology files that received a final recommendation between 2015-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)

Appendix

Files that submitted for criteria change and their corresponding prior submission

Brand Name	Generic Name	CDA-AMC Recommendation	CDA-AMC Recommendation Date	CDA Link	Indication	Reason for Subsequent Submission
Radicava	edaravone	Positive	2019-03-27	https://www.cda-amc.ca/edaravone	Amyotrophic lateral sclerosis	First
Radicava	edaravone	Positive	2022-12-22	https://www.cda-amc.ca/edaravone-0	Amyotrophic lateral sclerosis	Formulation change (IV to Oral)
Repatha	evolocumab	Positive	2016-02-19	https://www.cda-amc.ca/evolocumab	Hyperlipidemia	First
Repatha	evolocumab	Positive	2024-08-08	https://www.cda-amc.ca/evolocumab-1	Hyperlipidemia	Criteria change - reassessment
Revestive	teduglutide	Positive	2016-07-27	https://www.cda-amc.ca/teduglutide	Short bowel syndrome	First
Revestive	teduglutide	Positive	2019-11-19	https://www.cda-amc.ca/teduglutide-0	Short bowel syndrome	Age group expansion - older to younger
Spinraza	nusinersen	Positive	2017-12-22	https://www.cda-amc.ca/nusinersen	Spinal muscular atrophy	First
Spinraza	nusinersen	Positive	2019-02-27	https://www.cda-amc.ca/nusinersen-0	Spinal muscular atrophy	Age group expansion - younger to older; criteria change; resubmission
Spinraza	nusinersen	Negative	2022-08-11	https://www.cda-amc.ca/nusinersen-1	Spinal muscular atrophy	Age group expansion - younger to older; reassessment
Trikafta	elexacaftor / tezacaftor / ivacaftor and ivacaftor	Positive	2021-08-30	https://www.cda-amc.ca/elexacaftor-tezacaftor-ivacaftor-and-ivacaftor	Cystic fibrosis	First
Trikafta	elexacaftor/tezacaftor/ivacaftor and ivacaftor	Positive	2022-06-17	https://www.cda-amc.ca/elexacaftortezacaftorivacaftor-and-ivacaftor	Cystic fibrosis	Age group expansion - older to younger
Trikafta	elexacaftor/tezacaftor/ivacaftor and ivacaftor	Positive	2023-11-24	https://www.cda-amc.ca/elexacaftortezacaftorivacaftor-and-ivacaftor-0	Cystic fibrosis	Age group expansion - older to younger
Trikafta	elexacaftor/tezacaftor/ivacaftor and ivacaftor	Positive	2024-10-17	https://www.cda-amc.ca/elexacaftortezacaftorivacaftor-and-ivacaftor-1	Cystic fibrosis	Different subtype

Data Sources:

- CDA-AMC Reimbursement Reviews.
- MORSE Consulting Data Intelligence Tool.

Methodology:

- Results includes all non-oncology files that received a final recommendation between 2015-01-01 and 2025-12-31. Non-sponsored submissions, RFAs, and files have been excluded.
- Files were categorized by whether the drug had a prior review completed after 2015-01-01 and classified by reason for subsequent review (criteria change, resubmission, or new indication). Two reviewers categorized criteria change submissions into subtypes including age group expansion, new subtype, etc. (see appendix for list of criteria change submissions)

Thank you!

Toronto | Ottawa

Lana@morseconsulting.ca
https://morseconsulting.ca