

# Fee Schedule for CADTH Pharmaceutical Reviews

December 2020

## Record of Updates

Date	Summary of revisions
December 3, 2020	<ul style="list-style-type: none"> <li>Revisions to reflect renaming of CADTH reimbursement review process.</li> </ul>
October 29, 2020	<ul style="list-style-type: none"> <li>Postponement of the schedule D fee for pCODR reconsiderations until the April 2021 expert committee meetings.</li> </ul>
September 30, 2020	<ul style="list-style-type: none"> <li>Revisions to reflect the alignment of milestone 2 for invoicing oncology and non-oncology application fees.</li> </ul>
June 25, 2020	<ul style="list-style-type: none"> <li>Discontinuation of the schedule B fee for applications received on or after June 30, 2020.</li> <li>Notice that a schedule D fee will apply for requests for reconsiderations that are filed by industry sponsors for pCODR applications targeting the October 2020 expert committee meeting.</li> <li>New schedule F fee for drugs that are reviewed through <i>the CADTH Process for Drugs with Expanded Health System Implications</i>.</li> </ul>
April 29, 2020	<ul style="list-style-type: none"> <li>Annual fee adjustment based on the Consumer Price Index</li> </ul>
January 9, 2020	<ul style="list-style-type: none"> <li>Revisions to reflect interim process for plasma protein products and process for cell and gene therapies.</li> </ul>
March 28, 2019	<ul style="list-style-type: none"> <li>Annual fee adjustment based on the Consumer Price Index</li> </ul>
March 28, 2018	<ul style="list-style-type: none"> <li>Annual fee adjustment based on the Consumer Price Index</li> </ul>
February 13, 2018	<ul style="list-style-type: none"> <li><i>Guidelines on Application Fees for CADTH Pharmaceutical Reviews</i> replace the separate application fee guidelines for the CDR and pCODR programs.</li> <li>Reduced fee for the new biosimilar review process</li> <li>All submissions and resubmissions filed by manufacturers are subject to an application fee irrespective of the date of approval by Health Canada.</li> </ul>
November 13, 2017	<ul style="list-style-type: none"> <li>All resubmissions that are filed by manufacturers on or after January 2, 2018 will be subject to an application fee.</li> </ul>
March 5, 2015	<ul style="list-style-type: none"> <li>Original <i>Guidelines for Manufacturers on Application Fees for the pan-Canadian Oncology Drug Review</i></li> </ul>
September 2, 2014	<ul style="list-style-type: none"> <li>Original <i>Guidelines for Manufacturers on Application Fees for the CADTH Common Drug Review</i></li> </ul>

CDR = Common Drug Review; pCODR = pan-Canadian Oncology Drug Review programs.

## 1. Introduction

This document provides guidelines to industry sponsors on the application fees for the review of an application filed for review through one of the following CADTH programs:

- Common Drug Review (CDR)
- pan-Canadian Oncology Drug Review (pCODR)
- Interim Plasma Protein Product Review (PPP)
- CADTH Process for Drugs with Expanded Health System Implications

CADTH may amend, from time to time, the *Fee Schedule for CADTH Pharmaceutical Reviews* and all matters related to the review processes. Amendments to, and clarifications of, the *Fee Schedule for CADTH Pharmaceutical Reviews* may be effected by means of directives (called [CADTH Pharmaceutical Reviews Update](#)) issued by CADTH on an as-needed basis between formal revisions of the document. Any changes to the *Fee Schedule for CADTH Pharmaceutical Reviews* will be applied prospectively.

The application fees for CADTH pharmaceutical reviews were established to ensure that the appropriate amounts of fees are being recovered from the sponsors in accordance with the mandate of the Conference of Deputy Ministers of Health. The fees will supplement existing federal, provincial, and territorial funding.

### 1.1 Scope

This document applies to all applications filed by industry sponsors that require a review as per the descriptions provided for the fee schedules presented in Table 1. The *Fee Schedule for CADTH Pharmaceutical Reviews* must be read in conjunction with the following documents found on the CADTH website.

- [Procedures for CADTH Reimbursement Reviews](#)
- [Procedures for the CADTH Common Drug Review and Interim Plasma Protein Product Review](#) (files received before October 26, 2020)
- [Procedures for the CADTH pan-Canadian Oncology Drug Review](#) (files received before October 20, 2020)
- [CADTH Process for Drugs with Expanded Health System Implications](#)

### 1.2 Background

Application fees are required for all drug submissions and resubmissions filed by industry sponsors for review through CADTH's reimbursement review processes, which are pan-Canadian evidence-based processes for conducting consistent, clear, objective, and rigorous reviews of the clinical evidence, cost-effectiveness, and patient perspectives on these drugs. Application fees will not apply to any submission, resubmission, or request for advice filed by the public drug programs or tumour groups.

## 2. Implementation Guidelines

This section provides information on the fee amounts, the types of fees charged, and guidelines on refunds.

### 2.1 General Contact Information

For questions regarding invoicing and the timing of the application fees payment or questions about your account, please contact Accounts Receivable by phone at 613 226 2553, ext. 1314; fax at 613 226 5392; or email at [accountsreceivable@cadth.ca](mailto:accountsreceivable@cadth.ca). Please have your customer and invoice numbers readily available.

For questions regarding the type of fee charged for your application, please contact CADTH Central Intake by email at [requests@cadth.ca](mailto:requests@cadth.ca).

### 2.2 Fee Payment Procedures

All payments must be made in Canadian funds. Payments made by electronic fund transfer are preferred. Please contact [accountsreceivable@cadth.ca](mailto:accountsreceivable@cadth.ca) to discuss other payment options.

#### 2.2.1 Application Fee Schedule

Application fees will be charged based on the schedule in Table 1, plus applicable taxes. Applicable taxes include GST/HST and/or QST. The application fee schedule provides broad guidance on the fee schedules. CADTH reserves the right to make case-by-case determinations as to the applicable fee schedule.

**Table 1: Application Fee Schedule**

Schedule	Application Type	Fee
<b>A</b>	Application reviewed through the standard review process <sup>a</sup>	\$73,520
<b>C</b>	Application reviewed through the tailored review process	\$36,760
<b>D</b>	Request for reconsideration of a draft recommendation <sup>b</sup>	\$7,150
<b>E</b>	Application reviewed through the cell or gene therapy process <sup>c</sup>	\$108,890
<b>F</b>	Application reviewed through the process for drugs with expanded health system implications <sup>c</sup>	\$128,500

Note: A case-by-case assessment may be made to the fee schedule, where there are multiple indications included in one submission.

<sup>a</sup> All submissions and resubmissions reviewed through the standard review process that are received on or after June 30, 2020 will be subject to a schedule A application fee (the schedule B application fee has been discontinued).

<sup>b</sup> Currently applied for requests for reconsideration of an embargoed recommendation in the CDR and PPP processes and not applied in the pCODR process.

<sup>c</sup> Eligibility for applications filed under schedules E or F must be determined by CADTH prior to filing the submission.

CADTH increases application fees annually beginning on April 1<sup>st</sup> based upon fluctuations in the Consumer Price Index (CPI) determined by the Bank of Canada “Total CPI.” The increase shall be based on the average monthly increase in the CPI for the preceding April to January. The revised fee schedule will take effect on April 1<sup>st</sup> or when it is made available for the current year.

Fees will be charged at two process milestones for all fee schedules with the exception of schedule D fees, which will be charged at one milestone. Table 2 sets out the milestones.

**Table 2: Milestones for Payment of CADTH Application Fees**

Schedule	Milestone 1			Milestone 2			Total Fees
	Description	Per Cent Due	Amount Due	Description	Per Cent Due	Amount Due	
<b>Applications Received on or after October 26, 2020 (Non-oncology) or October 20, 2020 (Oncology)</b>							
A	Initiation of review	70%	\$51,464	Draft reports sent to sponsor	30%	\$22,056	\$73,520
C			\$25,732			\$11,028	\$36,760
E			\$76,223			\$32,667	\$108,890
F			\$89,950			\$38,550	\$128,500
D	Request accepted	100%	\$7,150	Not applicable	0%	\$0	\$7,150
<b>Applications Received before October 26, 2020 (Non-oncology) or October 20, 2020 (Oncology)</b>							
A	Initiation of review	70%	\$51,464	Draft reports sent to sponsor (CDR and PPP) or checkpoint meeting (pCODR)	30%	\$22,056	\$73,520
B <sup>a</sup>			\$41,174			\$17,646	\$58,820
C			\$25,732			\$11,028	\$36,760
D	Request accepted <sup>b</sup>	100%	\$7,150	Not applicable	0%	\$0	\$7,150
E	Initiation of review	70%	\$76,223	Draft reports sent to sponsor	30%	\$32,667	\$108,890
F			\$89,950			\$38,550	\$128,500

<sup>a</sup> All submissions and resubmissions reviewed through the standard review process that are received on or after June 30, 2020 will be subject to a schedule A application fee (the schedule B application fee has been discontinued).

<sup>b</sup> Currently applied for requests for reconsideration of an embargoed recommendation in the CDR and PPP processes and not applied in the pCODR process.

## 2.2.2 Submission of Payment

An initial invoice for the application fee owing will be sent based on the schedule and milestone description noted in Table 2.

Payments by electronic fund transfer are preferred. New sponsors should contact [accountsreceivable@cadth.ca](mailto:accountsreceivable@cadth.ca) for financial information.

All CADTH application fees are due within 30 calendar days of receipt of an invoice. If fee payment is not received within 30 days, the following will occur:

- A reminder will be provided indicating that payment is past due. It is the sole responsibility of the sponsor to pay any fees by the due date and although it is CADTH's intention to send subsequent reminders of unpaid fees, it shall not be obligated to do so.
- If payment remains outstanding after 45 calendar days, all work on the review will be temporarily suspended. Once a review is suspended, there is no assurance that the review will be completed in time for the originally targeted CADTH expert review committee meeting. If the review of an application has been temporarily suspended due

to the non-payment of fees, CADTH makes no commitments or guarantees as to the date on which such work will be resumed, or the expert committee meeting at which the application will be considered.

- Once payment in full is received, CADTH will resume its work on the suspended application as soon as it can be reasonably accommodated based on available resources and application volumes.
- In the case of a request for reconsideration, the expert committee recommendation will not be issued until full payment is received by CADTH.

Please contact [accountsreceivable@cadth.ca](mailto:accountsreceivable@cadth.ca) to discuss payments that are not electronic fund transfers or credit cards.

If insufficient fees are received, all work on the application will cease until the issue has been resolved. Should the sponsor be unable or unwilling to provide the required fees, the application may be withdrawn by the sponsor or CADTH will cancel the review. The sponsor may refile the application at a future date with the appropriate fees, without prejudice. Fees paid by a cheque that is not cleared due to insufficient funds (NSF) will be considered outstanding. Any fees associated with the NSF cheque incurred by CADTH will be charged to the sponsor. Any other fees associated with stop-payment requests, closed account fees, or any other such charges will also be charged back to the sponsor. Post-dated payments will not be accepted. Any overpayments will be refunded to the sponsor.

**Credit card payments (Visa, MasterCard) are accepted if the following information is provided:**

- cardholder's full credit card number
- cardholder's name (as it appears on the credit card), address, and telephone number
- expiry date of the credit card
- CVD number (on the back of the credit card).

To pay by credit card, please complete the appropriate section on the invoice and return it to CADTH at the address provided in this document or call CADTH Accounts Receivable at 613 226 2553, ext. 1314.

**Wire payments** of invoiced fees will be accepted only when wired in Canadian funds, as specified on the invoice.

Please include your company name, product name, CADTH project code, and invoice number with any wire payments.

Please ensure all service charges — including fees charged by your bank or any intermediary banks — are covered by your payment. CADTH is not responsible for any fees charged during the transfer process. Failure to pay the full amount outstanding will result in a balance owing on your account. Any payments sent in non-Canadian funds will be rejected. If problems occur with the transaction, please contact TD Canada Trust at 613 783 6619.

### 2.2.3 Performance Metric for CADTH Review Processes

Subject to the exceptions set forth in Table 4, which follows, non-compliance with the metric noted in Table 3 will result in a refund.

**Table 3: CADTH Performance Metrics**

Process	Milestones	Performance Metric	Compliance Target	Refund for Non-Compliance
CDR pCODR PPP	<p><b>Applications filed on or after October 26, 2020 (non-oncology) or October 20, 2020 (oncology):</b> Date the file is accepted for review by CADTH to the date the draft recommendation is issued to the sponsor and drug programs.</p> <p><b>Applications filed before October 26, 2020 (non-oncology) or October 20, 2020 (oncology):</b> Date the file is accepted for review by CADTH to the date the embargoed recommendation (CDR and PPP) or initial recommendation (pCODR) is issued.</p>	180 calendar days	95%	25% of the application fee payable back to the sponsor
Expanded Health System Implications	Date the file is accepted for review by CADTH to the date the draft recommendation is issued.	270 calendar days		

CDR = CADTH Common Drug Review; pCODR = CADTH pan-Canadian Oncology Drug Review; PPP = Interim Plasma Protein Product Review

There may be instances in which CADTH is prevented from achieving the performance metric because of circumstances beyond the reasonable control of CADTH, including, and without limitation, those circumstances set forth in the following Table 4. CADTH shall not be in breach of the performance metrics and shall not incur any liability to the sponsor or be responsible for any refund of application fees if and to the extent it is delayed and prevented from achieving the performance metrics due to circumstances beyond its control. During the period that such circumstances continue, the timelines shall be suspended. CADTH shall resume its work as soon as is reasonably possible and the performance metric timelines shall resume from the date on which CADTH is reasonably able to resume its work. As the embargoed recommendation will not be issued until the Notice of Compliance (NOC) or NOC with conditions (NOC/c) has been received by CADTH, there may be situations where CADTH is unable to issue the expert committee's recommendation within 180 calendar days as result of the category 1 requirements not being complete. In such circumstances, the sponsor will not be entitled to a refund.

**Table 4: Factors That May Influence CADTH Review Timelines**

Scenario
Voluntary withdrawal by the sponsor
Time required for the sponsor to provide additional information
Temporary suspension of a review by CADTH due to incomplete information
Substantial deviation between the proposed indication provided at the time of filing a submission on a pre-NOC basis and the final indication approved by Health Canada
Temporary suspension of a review by CADTH due to non-payment of the application fee
Deferral of the recommendation by the expert committee pending clarification on specific issues
Withdrawal of marketing authorization for a drug by Health Canada
Non-issuance of marketing authorization by Health Canada
Delay in issuing marketing authorization by Health Canada
Submission requirements (e.g., final product monograph) not finalized in time for CADTH to achieve the performance target

NOC = Notice of Compliance.

Please refer to the *Procedures for CADTH Reimbursement Reviews* and the *CADTH Process for Drugs with Expanded Health System Implications* for details regarding each of the scenarios noted in Table 4.

There may be other factors not included in the preceding Table 4 that are beyond CADTH's control and may impact the timing of a review. The determination as to whether a circumstance leading to a delay is beyond the reasonable control of CADTH shall be made by CADTH, acting reasonably, and shall be final and binding on the sponsor and all other parties. CADTH shall advise the sponsor in writing, as soon as practicable after such circumstances arise, of the delay and the circumstances beyond the control of CADTH that have resulted in the delay.

### 2.2.4 Refunds of Application Fees

Except as expressly provided for in this guidance document, application fees are non-refundable regardless of the CADTH final recommendation.

Sponsors who withdraw from the process after the review has been initiated and before reaching milestone 2 shall receive a refund of 50% of the total amount invoiced. Those who withdraw on or after milestone 2 shall not receive a refund. Schedule D fees are always non-refundable.

**Table 5: Details Regarding Refunds for CADTH Application Fees**

Refund Amount	Time of Withdrawal From CADTH Review Processes
50% refund	Before milestone 2
No refund	On or after milestone 2

## 2.3 Deferred Fees and Fee Exemptions

No application fees are eligible for any fee deferral or exemptions.