CADTH PAN-CANADIAN ONCOLOGY DRUG REVIEW

Guidelines for Manufacturers on Application Fees for the CADTH pan-Canadian Oncology Drug Review

APRIL 2015

CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

1. INTRODUCTION

This document provides guidelines to manufacturers on the application fee for the review of a drug submission or resubmission filed with the CADTH pan-Canadian Oncology Drug Review (pCODR). CADTH may amend, from time to time, the Guidelines for Manufacturers on Application Fees for the CADTH pan-Canadian Oncology Drug Review (hereafter referred to as the pCODR Guidelines on Application Fees) and all matters related to the pan-Canadian Oncology Drug Review. Amendments to, and clarifications of, the Guidelines on Application Fees may be effected by means of directives (called pCODR Communications) issued by CADTH on an "as needed" basis between formal revisions of the document. Any changes to the pCODR Guidelines on Application Fees will be applied prospectively.

The pCODR Guidelines on Application Fees were established to ensure that the appropriate amounts of CADTH pCODR fees are being recovered from the applicants in accordance with the mandate of the Conference of Deputy Ministers of Health. The fees will supplement existing provincial and territorial funding, and will be used to help finance an increase in the number of cancer drugs CADTH reviews annually.

1.1 Scope

This document applies to all drug review applications filed by manufacturers with the CADTH pCODR for drug submissions and resubmissions. The pCODR Guidelines on Application Fees must be read in conjunction with the following documents found on CADTH's website:

- *pCODR Submission Guidelines*
- *pCODR Procedures*.

1.2 Background

Application fees are required for all drug submissions and resubmissions filed by manufacturers for review through the CADTH pCODR process, which is a pan-Canadian evidence-based, cancer drug review process designed to bring consistency and clarity to the assessment of cancer drugs by reviewing clinical evidence, cost-effectiveness and patient perspectives, and using this information to make recommendations to Canada's provinces and territories (except Quebec) in guiding their funding decisions. These fees are meant to offset some of the costs related to the drug review. Application fees will not apply to any submission or resubmission filed by the CADTH pCODR Provincial Advisory Group and provincially-based 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 613 226 5392, or email at 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 phone 613 226 2553, fax 613 226 5392, or email at requests@cadth.ca.

2.2 Fee Payment Procedures

All payments must be made in Canadian funds. Payments must be made payable to either "CADTH" or the "Canadian Agency for Drugs and Technologies in Health."

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, or QST.

An application fee will apply to a drug manufacturer submitting an application for a submission or resubmission of cancer drugs/indications (including a submission or resubmission of new indication that is not likely to be submitted to Health Canada for review) to the pCODR program for review received on or after **April 1, 2015**.

Table 1: Application Fee Schedule

Schedule [a]	Application Type [b]	Fee
A	**Standard pCODR reviews** Submission for a new drug for review of a single indication or multiple drug products to be used in combination (e.g., new chemotherapy protocol)	$72,000
B	Each subsequent submission for an indication, including in a new line of therapy (e.g., first-line, relapsed refractory, adjuvant, neoadjuvant),[c] filed at the same time or sequentially for the application types listed in schedule A **Note: includes a cancer drug with a new indication where sufficient clinical and economic evidence exists to make a submission for a drug that has already received market authorization in Canada (i.e., off-label indications)*	$57,600
	Resubmission based on new clinical information (not previously submitted or published) in support of improved efficacy or safety or new cost information that significantly impacts the cost-effectiveness of the drug	
C	**Additional pCODR Reviews:** Submission for a biosimilar	$36,000

[a] A case-by-case assessment may be made to the fee schedule where there are multiple indications submitted as one submission.
[b] Application types under schedules A and B would typically undergo a standard pCODR review. The various application fee schedules reflect the relative difference in estimated effort for the review of the various application types.
[c] When an application is filed for a new type of cancer or for an existing indication but within a new line of therapy (e.g., first-line treatment, relapsed or refractory disease, adjuvant use), an application fee of $57,600 (20% discount) will apply to each of the other

indications to be reviewed. This is irrespective of whether the additional indications are filed at the same time or sequentially or the status of the Health Canada review.

Fees will be charged at two pCODR process milestones for all submissions. Table 2 sets out the milestones.

Table 2: Milestones for Payment of CADTH pCODR Application Fees

Schedule	Milestone 1			Milestone 2			Total Fee
	Description	Per Cent Due	Amount Due	Description	Per Cent Due	Amount Due	
A	Submission Deemed Complete	70%	$50,400	Checkpoint Meeting is held	30%	$21,600	$72,000
B		70%	$40,320		30%	$17,280	$57,600
C		70%	$25,200		30%	$10,800	$36,000

2.2.2 Submission of Payment

An initial invoice for the application fee owing will be sent once a submission or resubmission accepted for review by CADTH has been deemed complete.

Payments are to be sent to:
CADTH
Attn: Accounts Receivable
600 – 865 Carling Avenue
Ottawa, ON
K1S 5S8
Canada

All CADTH pCODR application fees are due within 30 calendar days of receipt of an invoice. If fee payment for a submission or resubmission, 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 applicant 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 drug 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 pCODR Expert Review Committee (pERC) meeting. 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.

Acceptable forms of payment include cheques, money orders, international bank drafts, credit cards (Visa, MasterCard), and wire transfers. Only Canadian funds are accepted.

Cheques, money orders, and international bank drafts should be made payable to "CADTH" or the "Canadian Agency for Drugs and Technologies in Health." Cheques drawn from non-Canadian banks must be issued in coordination with a referenced Canadian bank (that is, referenced on the cheque); otherwise they will not be accepted. If insufficient fees are received, all work on the application will cease and the drug submission or resubmission will be returned

to the applicant, without prejudice to re-filing along with the appropriate fees. Fees paid by a cheque that is not cleared through the CADTH bank account due to insufficient funds (NSF) will be considered outstanding. Any fees associated with the NSF cheque incurred by CADTH will be charged to the manufacturer. Any other fees associated with stop payment requests, closed account fees, or any other such charges will also be charged back to the manufacturer. Post-dated payments will not be accepted. Any overpayments will be refunded to the applicant.

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.

To pay by credit card, please complete the appropriate section on the invoice and return it to CADTH at the address provided above 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, pCODR submission identifier 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 Metrics for the CADTH pan-Canadian Oncology Drug Review Process

Table 3: Performance Metrics

Submissions	Performance Metric	Compliance Target	Refund for Non-Compliance
Screening of submission and "Submission Deemed Complete"	5 business days	100%	NA
Screening of resubmission and "Resubmission Deemed Complete"	10 business days	100%	NA
Date of "Submission Deemed Complete" to date of issuance of a pERC Initial recommendation	180 calendar days	95%	25% of the application fee payable back to the manufacturer

pERC = pCODR Expert Review Committee; NA = not applicable.

Subject to the exceptions set forth in Table 4 below, if a refund is payable to an applicant based on non-compliance with the metric (i.e., not meeting the timelines for date of "Submission

Deemed Complete" to date of issuance of a pERC Initial recommendation), a refund as per Table 3 will be provided.

There may be instances in which CADTH is prevented from achieving the performance metric due to circumstances beyond the reasonable control of CADTH, including without limitation those circumstances set forth in Table 4 below. CADTH shall not be in breach of the performance metrics and shall not incur any liability to the applicant 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 reasonably possible and the performance metric timelines shall resume from the date on which CADTH is reasonably able to resume its work.

Table 4: Factors[a] That May Influence pCODR Timelines

Scenario
• Voluntary withdrawal by the applicant
• 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
• Time required for the applicant 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
• Deferral of the recommendation by pERC pending clarification on specific issues
• Temporary suspension of a review by CADTH due to non-payment of the application fee

pERC = pCODR Expert Review Committee; NOC = Notice of Compliance.
[a] Further context for these factors is provided in the *pCODR Procedures*

Please refer to the pCODR Procedures and any pCODR Communications for details regarding each of the scenarios noted in Table 4.

There may be other factors not included in the preceding table 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 applicant and all other parties. CADTH shall advise the applicant 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* pERC Final Recommendation.

Subject to the exceptions set forth in Table 4, manufacturers who voluntarily withdraw from the pCODR process shall be entitled to receive a partial refund of the application fees in the following circumstances:

- Those who voluntarily withdraw from the pCODR process after initiation of a review and before the Checkpoint Meeting is held with the manufacturer shall receive a refund of 50% of the total amount invoiced.

- Those who voluntarily withdraw after the Checkpoint Meeting is held with the manufacturer, but before the date of the initial pERC meeting at which the drug is scheduled to be reviewed, shall receive a refund of 25% of the total amount invoiced.

No refunds will be issued for voluntary withdrawal after the submission or resubmission has been initially reviewed by pERC.

Table 5: Details Regarding Refunds for CADTH pCODR Application Fees

Refund Amount	Time of Voluntary Withdrawal From the CADTH pCODR Process
50% refund	Before the pCODR Checkpoint Meeting is held with the manufacturer
25% refund	After the Checkpoint Meeting is held with the manufacturer, but before the targeted initial pERC meeting
No refund	On or after the date of the targeted initial pERC meeting

pCODR = pan-Canadian Oncology Drug Review; pERC = pCODR Expert Review Committee.

2.3 Deferred Fees and Fee Exemptions

Application fees for submissions and resubmissions are not eligible for any application fee deferral or exemptions.