CADTH and Canadian Blood Services Interim Plasma Protein Product Review Process

1. Background on Interim Process

CADTH and Canadian Blood Services (CBS) are pleased to announce the establishment of a new interim process for the review of plasma protein products (PPPs). The interim process builds upon the strengths of both agencies to provide stakeholders with an objective, transparent, evidence-informed review process for PPPs. The interim process will be in place while provincial and territorial governments (except Quebec) complete a review of PPPs and drug formulary processes in collaboration with CBS, CADTH, as well as other key stakeholders.

The objectives of the interim process for the review of PPPs are, as follows:

- promote efficiency within Canadian health technology assessment processes by seeking alignment of procedures, guidelines, and timelines
- facilitate greater transparency, collaboration, and information-sharing between CADTH, CBS, and stakeholders.

This document provides a brief overview of the new interim process.

2. Eligibility Under the Interim Process

Submission from manufacturers, also known as “sponsors,” for new categories to the CBS formulary will be assessed by CBS and CADTH using the current CBS Plasma Protein Product Selection eligibility criteria, subject to approval by the provincial and territorial governments (excluding Quebec) for a new category on the CBS formulary. The current eligibility criteria are that the product:

- is a biological drug manufactured from human plasma or a biological drug whose active ingredient(s) are functional equivalents of the foregoing, used in the practice of Transfusion Medicine, *and*
- is not carried in the health system already.

CBS and CADTH will initiate a review after confirmation by the Provincial and Territorial Blood Liaison Committee (PTBLC) on whether:

- the product meets the eligibility requirements for consideration as a new category on the CBS formulary, *or*
- whether the product would be reviewed by CBS as a new brand within an already approved category on the CBS formulary.

Manufacturers making product submissions with questions regarding whether or not a product is eligible for review through the interim process are asked to complete an eligibility request form and submit it to requests@cadth.ca. CADTH will forward the information to CBS for discussion with the PTBLC. Eligibility should be determined prior to requesting a pre-submission meeting or providing advance notification. If it has been determined that the product does not meet the eligibility criteria, the manufacturer can consider filing a submission through the CADTH Common Drug Review (CDR) process.

3. Interim Pre-submission Procedure

Pre-submission activities for the interim PPP process will be similar to the processes that are used in the CADTH CDR process. This includes the opportunity for a pre-submission meeting with CADTH and CBS anytime within 12 months of the anticipated date of filing the submission. To request a pre-submission meeting, sponsors are required to complete a pre-submission meeting request form and submit it to CADTH at meetingrequests@cadth.ca.

In accordance with CADTH's advance notification processes, sponsors for plasma-related drugs are required to provide CADTH with a minimum of 30 business days of advance notice for anticipated submissions. To fulfill the advance notification requirement, manufacturers must complete the advance notification template in its entirety and submit it to CADTH (requests@cadth.ca). CADTH will subsequently inform CBS and provide it with the completed advance notification template.

4. Stakeholder Engagement

In accordance with CADTH's existing pharmaceutical review processes, the interim PPP process will include engagement with patient groups, clinical specialists, CBS, and public payers. These processes will occur in a similar manner to CADTH's existing CDR process; however, CADTH and CBS will continue to discuss the specific requirements related to the review of PPPs, and work together to jointly identify input needs from relevant patient groups and specialists with expertise in the diagnosis and management of the condition for which the PPP is indicated. In addition, the stakeholder input from the public payers will be provided through the PTBLC, together with relevant information from CBS as the formulary manager.

5. Interim Submission Requirements

The clinical, economic, and administrative submission requirements for the interim PPP process are similar to those used in the CADTH CDR process, with the exception of the following additional requirements:

- a budget impact report that provides an overall aggregate budget impact analysis (BIA) for the plasma product under review (i.e., a pan-Canadian analysis)
- a copy of the model used to produce the aggregate pan-Canadian BIA
- a reference list and copies of all supporting documentation used and/or cited in the BIA.

6. Interim Application and Screening Procedure

The application filing and screening procedures for plasma protein drugs will be identical to those currently used in the CDR the process. Sponsors must be registered (CADTH Collaborative Workspaces Registration) before filing a submission or resubmission. CADTH will provide a copy of the submission requirements to CBS to ensure that it has this information prior to the expert committee meeting.

All submissions filed by manufacturers for PPPs are subject to an application fee according to the fee schedule applied for the CDR process (for details, please consult fee schedule for CADTH reviews).

In accordance with CADTH's processes, the status and key dates for the review of PPPs will be posted on the CADTH website.

7. Interim Review Procedure

Table 1 indicates the targeted time frames for key tasks within the interim PPP process. The clinical and economic review processes will be completed in accordance with CADTH's standard review procedure (see the *Procedure and Submission Guidelines for the CADTH Common Drug Review*). As with CADTH's existing process, the sponsor will have the opportunity to review and comment on the draft reports prior to the expert review committee meeting.

CADTH will post the clinical and economic report(s) for all submissions reviewed through the process. The sponsor will be responsible for identifying any confidential information included in the reports.

Table 1: Targeted Timelines for the Interim Plasma Protein Product Review Process

Phase of Review	Key Milestone	Business Days
Screening and administration	Submission requirements received by CADTH	0
	Submission requirements screened for acceptance	10
	Review initiated	1 to 10
Review of submission or resubmission	Draft review report(s) prepared and sent to sponsor for comments	45
	Sponsor receives draft review report(s) and provides comments	7
	CADTH responds to comments[a] and final review report(s) prepared	7
Deliberation and recommendation	Expert committee brief completed and distributed	5
	Review of meeting materials and preparation of discussant reports	10
	Expert committee meeting	1
	Embargoed recommendation sent to the sponsor, CBS, PTBLC, and the drug plans	8 to 10
Embargo period and options	Embargo period	10 to 30[b]
	Request for clarification or request for reconsideration	Variable[c]
Finalizing and posting	Final recommendation issued to the sponsor, CBS, PTBLC, and the drug plans	5
	Final recommendation and review report(s) posted	2

CBS = Canadian Blood Services; PTBLC = Provincial and Territorial Blood Liaison Committee.
[a] Sponsors will be sent CADTH's responses eight (8) business days prior to the expert committee meeting.
[b] An extension of up to 20 business days may be requested to prepare a request for reconsideration (i.e., a total of 30 business days).
[c] The time frame required to address a request for clarification, or request for reconsideration, depends on the amount of work needed to address the request, as well as the available dates for expert committee meetings.

8. Interim Recommendation Procedure

The output from the process will be a recommendation from a subcommittee of the CADTH Canadian Drug Expert Committee (CDEC), which will be enhanced with two additional members with expertise in PPPs. This subcommittee will serve as an advisory body to CADTH that will issue recommendations and advice to inform reimbursement decisions for PPPs that are reviewed through the interim PPP process. The CDEC subcommittee, with two additional members with expertise in PPPs, will be referred to during this interim basis as the Canadian Plasma Protein Product Expert Committee, or CPEC.

The recommendation options available in the interim process for the review of PPPs will be the same as those currently used in CADTH's pharmaceutical review processes: that a drug be reimbursed; that a drug be reimbursed with conditions; or that a drug not be reimbursed. A confidential embargoed recommendation will be sent to the sponsor, CBS, and the PTBLC, and to the public drug plans, for information. The procedures for the embargo period and options for filing a request for reconsideration and/or clarification will be identical to those currently used in the CADTH CDR process.

9. Interim Implementation of Recommendations

Recommendations for products that would require a new category to the CBS formulary would be submitted to CBS and shared with PTBLC. As formulary manager, CBS will supplement recommendations with additional information and submit those to the PTBLC for review and decision by the Conference of Deputy Ministers. After the final recommendation has been issued, CADTH may provide implementation support for the PTBLC and CBS, as required. This support is distinct from the interim PPP process and is offered for the purposes of assisting CBS and PTBLC in operationalizing recommendations from CADTH and/or making reimbursement policy decisions. Examples of implementation support activities are described in section 14 of the *Procedure and Submission Guidelines for the CADTH Common Drug Review*.

10. Other Administrative Items

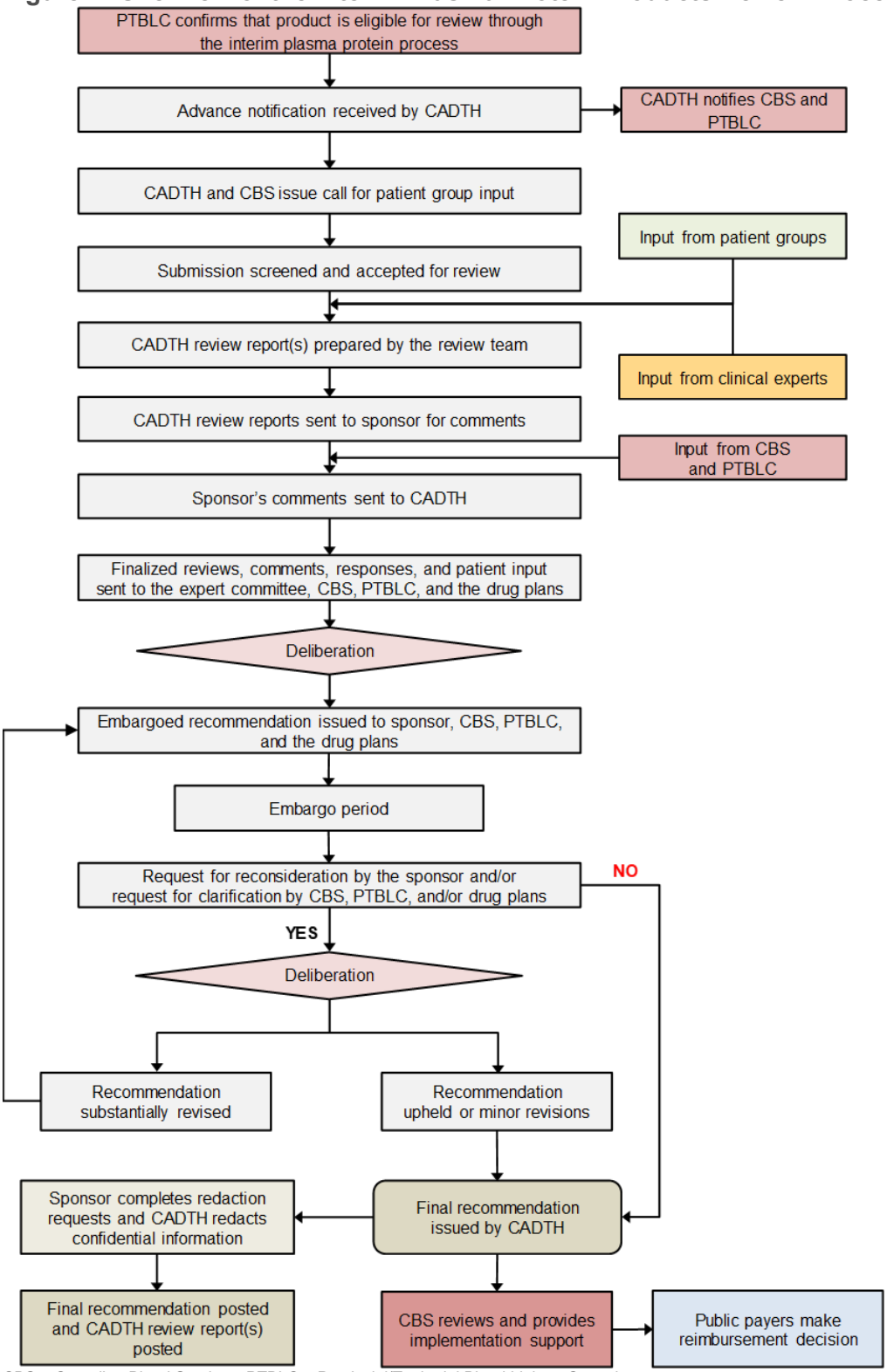
10.1 Temporary Suspension and Withdrawal

Procedures for temporary suspension and withdrawal from the interim PPP process are similar to those used in CADTH's existing CDR process and are described in the *Procedure and Submission Guidelines for the CADTH Common Drug Review.*

10.2 Confidentiality and Document Management

Confidential information obtained by CADTH for the purposes of the interim PPP process will be protected and handled in accordance with CADTH's confidentiality guidelines for the CADTH CDR. These guidelines are available in the *Procedure and Submission Guidelines for the CADTH Common Drug Review.*

Figure 1: Overview of the Interim Plasma-Protein Products Review Process



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