Update on the CADTH and Canadian Blood Services Interim Plasma Protein and Related Product Review Process

1. Background on the Interim Process

In November 2019, CADTH and Canadian Blood Services announced the establishment of a new interim process for the review of plasma protein and related products (PPRPs). This interim process was established to build upon the strengths of both agencies to provide stakeholders with an objective, transparent, evidence-informed review process for PPRPs. The interim process will be in place while provincial and territorial governments (except Quebec), in collaboration with Canadian Blood Services, CADTH, and other key stakeholders, complete a review of PPRP and drug formulary processes.

The objectives of the interim process for the review of PPRPs 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 among CADTH, Canadian Blood Services, and stakeholders.

This is a brief update on revisions to the name and eligibility criteria for the interim review process. There are no other changes to the interim process, and all reviews are completed in accordance with the *Procedures for CADTH Reimbursement Reviews*.

2. Revised Name of the Interim Process

The name of the interim process has been updated from the *Interim Plasma Protein Product (PPP) Review Process* to the *Interim Plasma Protein and Related Product (PPRP) Review Process.* This change has been made to align with the updated terminology used by Canadian Blood Services.

3. Revised Eligibility Criteria

The eligibility criteria for review through the interim process have been updated to reflect changes within the procedures used by Canadian Blood Services. Specifically, the process for

the review of “new brands” has been discontinued by Canadian Blood Services. The revised eligibility criteria for the interim process are described subsequently.

Submissions from manufacturers, also known as “sponsors,” for new categories and/or for new products that are determined to be in some way innovative to the Canadian Blood Services formulary will be assessed by Canadian Blood Services and CADTH using the Canadian Blood Services PPRP selection eligibility criteria, subject to approval by the provincial and territorial governments (excluding Quebec) on the Canadian Blood Services formulary. The 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;

Canadian Blood Services 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 and/or a new product that is determined to be in some way innovative on the Canadian Blood Services formulary.

Canadian Blood Services will confirm with the manufacturer if the product will also be reviewed through an RFP process for PRPPs in an approved category of products.

Manufacturers 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 Canadian Blood Services for discussion with the PTBLC. Eligibility should be determined before requesting a pre-submission meeting or providing advance notification. If it has been determined that the product does not meet the eligibility criteria as a PPRP, the sponsor can consider filing a submission through the CADTH Reimbursement Review process for a recommendation to inform reimbursement by the public drug programs.