



Network of  
Rare Blood Disorder  
Organizations

**Position Statement**

**DISTRIBUTION OF BLOOD, FRACTIONATED PRODUCTS AND  
THEIR REPLACEMENTS THROUGH CBS AND HÉMA-QUÉBEC  
FORMULARIES**

**November 2019 - Updated May 2021**

It is the position of the Network of Rare Blood Disorder Organizations (NRBDO) that Canadian Blood Services and Héma-Québec uphold their original mandates for the procurement and distribution of blood and plasma-derived therapies. As noted in the original Memorandum of Understanding, this includes “all whole blood and blood products, plasma and plasma products, and their respective artificial and substitute products.”

**BACKGROUND**

The NRBDO is a pan-Canadian coalition of not-for-profit organizations representing people with rare blood disorders and/or people with chronic conditions who are regular recipients of blood or blood products or their alternatives. Together, we represent many thousands of patients. As such we have had a vested interest in access to relevant therapies in Canada and internationally since forming in 2004.

Distribution and reimbursement of the cost of blood products, including all plasma-derived medicinal products (PDMPs) and their synthetic alternatives, has since 1998 occurred via Canadian Blood Services (CBS) and in Quebec, Héma-Québec (H-Q), as outlined in the Federal/Provincial/Territorial Memorandum of Understanding (MOU) on which these organizations were founded. Provinces and Territories jointly fund CBS and Héma-Québec to perform this function in our healthcare system. Having a pan-Canadian, scalable, cost-shared infrastructure and logistics network has ensured fair and equitable blood product access for Canadians, as well as assuring the best price from negotiating as a single entity.

The nature of products used to treat people with blood and bleeding disorders has evolved significantly over the last 70 years. New manufactured therapies that are safer, more efficacious and easier to administer continue to replace blood and plasma products. The development of monoclonal antibodies that mimic blood and plasma-derived products has raised the question among provincial and territorial health authorities as to whether this model of reimbursement should continue, or whether such therapies should be listed on provincial/territorial drug formularies.

There is no doubt among NRBDO members that this model of reimbursement should continue and expand to consistently include products that replace blood and plasma-derived therapies.

### **Mandates**

If one considers the MOU that defines the mandates of CBS and Héma-Québec, that is, to supply “artificial, substitute products” as well as the classical “plasma products”, or “replacement products” for “fractionated products,” it is clear that this agreement applies to novel products.

The Federal/Provincial/Territorial *Memorandum of Understanding (MOU)* that created Canadian Blood Services specifies that the following definition applies:

*“Blood” means whole blood and blood products, plasma and plasma products and their respective artificial and substitute products.*

The *MOU* reiterates the seven Ministerial Principles formally adopted by the Provincial and Territorial Ministers of Health in 1989, including:

*Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained.*

In Quebec, the legislation that created Héma-Québec stipulates that it should:

*“... sur demande du ministre de la Santé et des Services sociaux ou d'un organisme de gestion de l'approvisionnement en commun des établissements qu'il a désigné, à se procurer, entreposer et fournir aux établissements les produits de fractionnement ou les produits de remplacement dont ils ont besoin.”*

*“...on request by the Minister of Health and Social Services or a designated body that supplies designated establishments, to procure, store and supply to the designated establishments fractionated products or the replacements products that they require.”*

### **Equitable Access**

The primary purpose for the NRBDO's insistence on distribution through CBS and H-Q is to ensure equitable access to these therapies regardless of geographic or socio-economic status. If all blood, components, and plasma fractions are meant to be distributed free of charge to all Canadians, then that same principle must apply to the replacement products included in CBS and H-Q's mandates.

### **Timely Access to Novel Products**

Currently, each time a novel blood- or plasma- replacement product is approved by Health Canada, there is a significant delay while the review and reimbursement path is debated. It is in

the best interest of patients for timely access to novel therapies for there be clarity that all products that fit into this category proceed to the HTA process without this needless delay.

### **Budget/Cost-management**

Procurement and distribution through CBS and H-Q is also in the best interest of the provinces and territories. Not only do CBS and H-Q have “bulk buying power,” they have established a tender system that allows them to maximize the provincial blood product budgets and manage costs. It is consistent and efficient to keep replacements in this system, as reductions and related potential savings in blood- and plasma-derived products are realized within the same budget.

### **Vigilance**

Our separate system for the procurement and distribution of blood and plasma products was largely established by the Federal/Provincial/Territorial governments to manage the required surveillance procedures to ensure safety from donor to recipient. These procedures are arguably vital in the procurement and distribution of all biologics. CBS and H-Q’s systems allow for heightened tracking of products to manage the safety (including recall), potential shortages, and efficient utilization of these (typically) high-cost products.

### **CONCLUSION**

Under current and binding Federal/Provincial/Territorial agreements, all blood and plasma-derived products and their replacements must continue to be distributed through CBS and Héma-Québec and be reimbursed through provincial and territorial health budgets.

### **Endorsements**

Association of Hemophilia Clinic Directors of Canada (AHCDC)

Canadian Society Of Allergy And Clinical Immunology (CSASI)

Clinical Immunology Network-Canada (CINC)