Network of Rare Blood Disorder Organizations
Réseau des Associations Vouées aux Troubles Sanguins Rares

NRBDO RAVTSR

Position Statement
DISTRIBUTION OF FRACTIONATED PRODUCTS AND THEIR REPLACEMENTS THROUGH CBS AND HÉMA-QUÉBEC FORMULARIES
November 2019

It is the position of the Network of Rare Blood Disorder Organizations (NRBDO) that novel products including monoclonal antibodies and other products that are approved for use to replace blood and plasma-derived therapies, including gene therapy, should be procured and supplied by Canadian Blood Services and Héma-Québec, listed on their respective formularies, and their cost reimbursed similarly to other blood products and their substitutes.

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 health care system. Having a national, scalable, cost-shared infrastructure and logistics network has ensured fair and equitable blood product access for Canadians.

The nature of products used to treat people with blood and bleeding disorders has evolved significantly over the last 70 years. New manufactured therapies 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.

If one considers the legislation 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 legislation applies to these novel products.

Supporting regulations and legislation
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 établissement 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."

Conclusion

Under current legislation and regulation, 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 global health budgets.