AUGUST 2019

Cutaquig™ (preparation of human immunoglobulins) Notice of inclusion on the *Liste des produits du système du sang du Québec*

English summary

Une production de l'Institut national d'excellence en santé et en services sociaux (INESSS)

Direction des services de santé et de l'évaluation des technologies

This is the English summary of the guidance entitled Cutaquig[MC] (préparation d'immunoglobulines humaines) Avis d'introduction à la *Liste des produits du système du sang du Québec* published in August 2019.

The complete version of this guidance (in French) is available on the website of INESSS in the Publications section.

Membres de l'équipe projet

Auteurs principaux
Simon Bélanger, M. Sc., M.B.A.
Julie Nieminen, Ph.D

Collaborateurs internes
Sara Beha, M. Sc.
Phuong Hua, M. Sc.

Coordonnateur scientifique
Yannick Auclair, Ph. D

Adjointe à la direction
Mariève Simoncelli, B. Pharm, M. Sc.

Directrice
Michèle de Guise, M.D., FRCPC

Repérage d'information scientifique
Mathieu Plamondon, M.S.I.
Flavie Jouandon, *tech. doc.*

Soutien administratif
Christine Lemire

SUMMARY

Mandate

The Institut national d'excellence en santé et en services sociaux (INESSS) carried out an evaluation of Cutaquig™, a preparation of immunoglobulins administered by subcutaneous injection for the treatment of patients with primary immune deficiency (PID) and secondary immune deficiency (SID) who require immune globulin replacement therapy.

Evaluation process

Literature data and data provided by the manufacturer were reviewed to document the efficacy, safety and efficiency of Cutaquig™. Experiential and contextual data were gathered from experts.

Healthneed

Preparations of non-specific immunoglobulins (Igs) are indicated mainly for the treatment of patients with PID or SID. An immune deficiency, or immunodeficiency, is a weakened or impaired immune status. Immunodeficient individuals are predisposed to an increase in the rate and severity of infections, to immunological deregulation associated with an autoimmune disease, to aberrant inflammatory responses and to the formation of malignant tumours.

PID refers to any form of immunodeficiency caused by a defect in certain cells in the immune system, while SID refers to any form of acquired immunodeficiency caused by external factors, such as a disease or a medical treatment.

Immunoglobulin replacement therapy is recommended in adult and pediatric patients with PID or SID. A number of subcutaneously or intravenously administered immunoglobulin preparations are currently on the *Liste des produits du système du sang du Québec.*

Results

Efficacy

- No severe infections during Ig replacement therapy with Cutaquig™;
- Number of non-severe infections: 3.43 per patient/year;
- Results comparable to those for the other immunoglobulin preparations that are currently available.

Very low quality of evidence

Safety

- No serious adverse events associated with replacement therapy with Cutaquig™;
- Results comparable to those for the other immunoglobulin preparations that are currently available.

Very low quality of evidence

Quality of life

- Little or no change in the quality-of-life scores following replacement therapy with Cutaquig™;

  Very low quality of evidence

Assessment of therapeutic value

- The efficacy of subcutaneously administered immunoglobulin concentrates is equivalent to that of those administered intravenously;
- The subcutaneous route is generally associated with a better quality of life than the intravenous route;
- The experts consulted recognize the therapeutic value of Cutaquig™ as replacement therapy in cases of PID or SID. Ig preparations are considered interchangeable;
- However, according to the members of the expert group on blood system products, guidance on the use of Ig preparations is an issue. They stress that, regardless of the product chosen for distribution, a patient education program should be put in place.

Efficiency

- Based on a comparison of prices per gram of protein, Cutaquig™ is more efficient than its comparators.

Budget impact

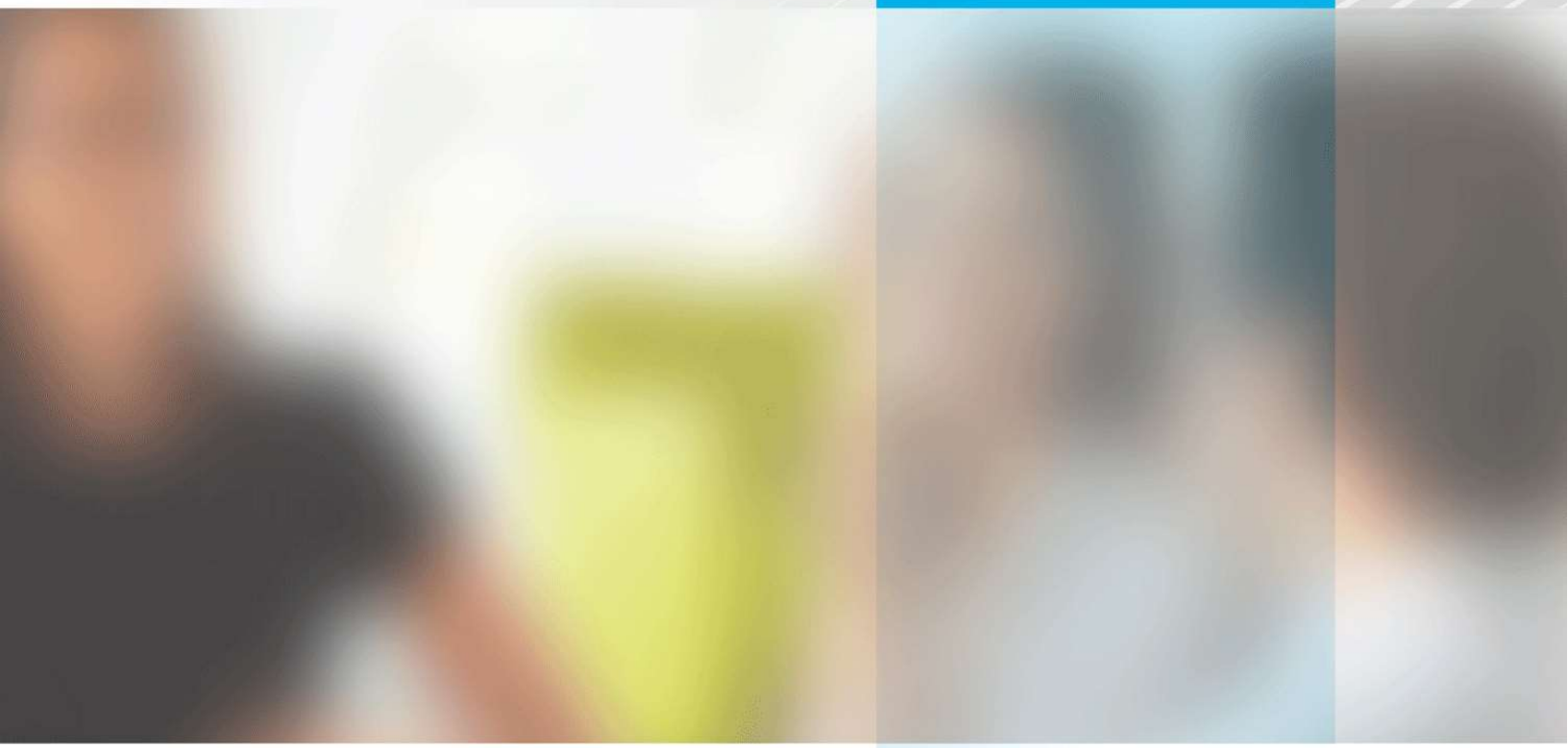
- The price of Cutaquig™ is $[redacted]/g, while that of Hizentra™ is $[redacted] and that of Cuvitru™ is $[redacted];
- If Cutaquig™ held [redacted]% of the shares of subcutaneous Ig market, one could expect a cost reduction of approximately $1 to $1.7 million per year, for an estimated total of $4 million over 3 years. If Cutaquig™ held [redacted]% of the market, one could expect a cost reduction of close to $14 million during this period.

Deliberation concerning Cutaquig™

The members of the Comité scientifique permanent de l'évaluation des médicaments aux fins d'inscription unanimously recognized the therapeutic value of Cutaquig™ for the treatment of patients with primary immune deficiency (PID) and secondary immune deficiency (SID) who require immune globulin replacement therapy. Consequently, the members are unanimously of the opinion that the blood system product Cutaquig™ should be added to the *Liste des produits du système du sang du Québec*.

Reasons for the unanimous position

- Two other subcutaneous Ig preparations are presently on the *Liste des produits du système du sang du Québec*.
- The therapeutic value of Cutaquig™ was considered comparable to that of the currently available products, based mainly on the efficacy, safety and quality-of-life data examined.
- Based on a comparison of prices per gram of protein, Cutaquig™ is more efficient than its comparators.
- Cutaquig™ could lead to cost reductions of $1 to $14 million during each of the next three years, depending on the market shares captured.



Siège social

2535, boulevard Laurier, 5e étage
Québec (Québec) G1V 4M3
418 643-1339

Bureau de Montréal

2021, avenue Union, 12e étage, bureau 1200
Montréal (Québec) H3A 2S9
514 873-2563
inesss.qc.ca

Institut national d'excellence en santé et en services sociaux
Québec