Atlantic Ministries of Health Common Policy for Intravenous and Subcutaneous Immunoglobulin

The following Atlantic Ministries of Health Common Policy was developed in consultation with Atlantic clinical experts and specifies patient eligibility for access to publicly funded intravenous/subcutaneous immunoglobulin.

Rationale

Intravenous/subcutaneous immunoglobulins (IVIG/SCIG) are blood products made from pooled human plasma and as such, are not risk-free to patients. In appropriately selected patients and clinical settings, IVIG/SCIG therapy can be lifesaving. However, serious adverse reactions can occur, such as: hemolysis, renal failure, aseptic meningitis, anaphylaxis, and thromboembolic events. Patients must be monitored throughout their treatment to confirm efficacy of the product and that the desired clinical outcomes are achieved.

Objective

To manage utilization of IVIG/SCIG in a safe and sustainable manner through clarification of the parameters under which IVIG/ SCIG may be dispensed and used in the Atlantic Provinces.

Scope

This Atlantic Ministries of Health Common Policy applies to the distribution and use of IVIG/SCIG by all medical professionals in the Atlantic Provinces.

Policy Statement #1 – Screening of Indicated Medical Conditions

Requests for IVIG/SCIG to treat indicated conditions in the *Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin (IVIG/SCIG)* document must be screened prior to dispensing product to ensure that all specific criteria have been met, and that the dose, duration and frequency of therapy are in accordance with the indications and criteria established by the Atlantic clinical experts.

Policy Statement #2 – Screening of Possibly Indicated Medical Conditions

Requests for IVIG/SCIG to treat possibly indicated conditions in the *Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin (IVIG/SCIG)* document must be screened prior to dispensing product to ensure that all specific criteria have been met, and that the dose, duration and frequency of therapy are in accordance with the indications and criteria established by the Atlantic clinical experts. Requests for IVIG/SCIG to treat the *"possibly indicated conditions"* will be approved for 3 months only at which time the treating physician must reevaluate the patient's progress and complete an outcome questionnaire

form. If treatment is deemed ineffective, IVIG/SCIG will be discontinued. *See policy statement #5.*

Policy Statement #3 – Screening of All Other Conditions

The use of IVIG/SCIG for all other conditions must be reviewed and approved by a designated clinical expert. Approval will be made only on the basis of extenuating circumstances and where there is reasonable evidence indicating that IVIG/SCIG may be of therapeutic value. All other orders will be declined.

Physicians requesting the release of IVIG for conditions that do not meet Policy Statement #1 or #2 must provide the following:

- Reasonable evidence for efficacy,
- Informed written consent from the patient for the use of IVIG/SCIG as an unlicensed agent for the treatment of an unapproved condition

If such a request is approved by the designated clinical expert, the treating physician must reevaluate the patient's progress after 3 months and complete an outcome questionnaire form. If treatment is deemed ineffective, IVIG/SCIG will be discontinued. *See policy statement #5.*

Policy Statement #4 – Dosing Through Adjusted Body Weight Calculation

The maximum amount of IVIG/SCIG administered should reflect adjusted body weight dosing in patients with a minimum height of 152.4 cm (60 inches) and/or a minimum weight of 45 kg.

"Adjusted body weight" or "Dosing body weight" dosing are common practices used by pharmacists when determining drug doses in obese patients, based on the fact that some drugs, like IVIG, have very little distribution into adipose tissue (fat).

Using dosing body weight, patients will receive a lower dose of IVIG/SCIG than they would if dosed according to their actual body weight. Actual body weight will be used to determine doses for patients less than 152.4 cm and/or less than 45 kg.

This dosing schema will improve patient safety by reducing unnecessary exposure to higher doses of IVIG/SCIG which are associated with greater incidence of adverse events including hemolysis and thrombosis. An IVIG/SCIG Dosing Calculator based on adjusted body weight, is available here: https://docs.nshealth.ca/IVIG/

Policy statement #5 –Clinical Outcome Evaluation

A patient receiving IVIG/SCIG for a possibly indicated condition, or under extenuating circumstances, must have a clinical outcome evaluation completed by the treating clinician 3 months after the initial prescription, 6 months after that date and then every 12 months thereafter to ensure:

- IVIG/SCIG remains of therapeutic value; and

- The minimal effective dose of IVIG/SCIG is being prescribed
- The evaluation must accompany the requisition/order for product

Regular evaluations are required to ensure that the treatment continues to be effective and appropriate. If therapeutic value is not realized through IVIG/SCIG therapy, the therapy will be discontinued and alternative treatments must be explored.

Policy Statement #6 – Outdating of Product

There must be no expiry (outdating) of IVIG/SCIG. IVIG/SCIG has an approximate shelf-life of two years. Dispensing authorities must implement inventory management practices that prevent the expiry of product.

Policy Statement #7 – Reporting

IVIG/SCIG is a blood-derived product and not risk-free to patients; therefore, all usage must be tracked and reported.

Hospitals must report their use of IVIG/SCIG into the Intravenous Immunoglobulin Network (IVIN) database housed at the Nova Scotia Provincial Blood Coordinating Team (NSPBCT). Transfusion reactions associated with IVIG/SCIG must be reported to the Transfusion Medicine Service and the applicable authority in each jurisdiction.