Government of Newfoundland and Labrador

Department of Health and Community Services
Provincial Blood Coordinating Program

REVIEW AND APPROVAL OF REQUESTS FOR IVIG FOR ADULTS	NLBCP-007

Office of Administrative Responsibility	Issuing Authority
Medical Advisor to the Provincial Blood Coordinating Program	Dr. Lucinda Whitman
Manager, Provincial Blood Coordinating Program	Daphne Osborne
Author	Melissa Leonard
Effective Date	2019-04-29
Version	3.0
Review Due Date	2021-04-29

Overview

The purpose of this policy is to outline the process to be used for the review and approval of requests for intravenous immunoglobulin (IVIG) for adult patients. In May 2018, the Atlantic Ministries of Health Common Policy for Intravenous and Subcutaneous Immunoglobulin was signed by all Atlantic Deputy Ministers of Health. The Atlantic Blood Utilization Strategy (ABUS), in consultation with Atlantic clinical experts, prepared this document to ensure IVIG and SCIG are used for appropriate indications and in doses recommended by the current literature and expert clinical opinion. The Common Policy will be referenced throughout this policy.

Policy

1. All facilities shall have an established policy, which comply with Provincial Blood Coordinating Program (PBCP) policies, for the review and approval of requests for IVIG.
2. All requests for IVIG shall be submitted to the Transfusion Medicine Laboratory (TML) for review using the pre-printed IVIG request form (PPO). All required information must be provided. In the case of missing information, the PPO must be returned to the ordering physician/patient care area to be completed.
3. IVIG patients shall be dosed through the adjusted body weight calculation. The maximum amount of IVIG administered shall 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.
4. The TML shall check the dose using the NLPBCP IVIG dose calculator or facility equivalent.
5. Requests for IVIG to treat **indicated conditions** in the Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin (IVIG/SCIG) document shall 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.
6. Requests for IVIG to treat **possibly indicated conditions** in the Atlantic Clinical Indications and Criteria document shall 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. These requests will be approved for three (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 will be discontinued.

7. The use of IVIG for all other conditions shall 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 may be of therapeutic value. All other orders will be declined.
8. In order to be considered for conditional approval for a condition that is not indicated or not possibly indicated, the requesting physician must provide:
   8.1. Reasonable evidence for efficacy; and
   8.2. Informed written consent from the patient for the use of IVIG as an unlicensed agent for the treatment of an unapproved condition.
9. If requests for conditions that are not indicated or not possibly indicated are approved by the designated clinical expert, the treating physician shall reevaluate the patient's progress after three (3) months and complete an Outcome Questionnaire form. If treatment is deemed ineffective, IVIG will be discontinued.
10. A patient receiving IVIG for a possibly indicated condition, or under extenuating circumstances, shall have a clinical outcome evaluation completed by the treating clinician:
    10.1. Three (3) months after the initial prescription;
    10.2. Six (6) months after that date; and
    10.3. Every 12 months thereafter.
11. The TML shall forward the Outcome Questionnaire to the prescribing physician or designate four weeks before the three month trial period will end. If treatment is continued past the three month trial, the Outcome Questionnaire shall be sent, again, four weeks before it is required for subsequent prescriptions.
12. The prescribing physician or designate shall complete the Outcome Questionnaire and return to TML no later than one week before treatment is expected to resume.
13. The TML shall forward completed Outcome Questionnaire to PBCP for review.
14. PBCP shall review with the Medical Advisor to determine if criteria are met to continue IVIG therapy. If necessary, a consult with Nova Scotia expert panel will occur.
15. Completed Outcome Questionnaires shall be attached to next completed PPO.
16. Physician orders (PPOs) shall be valid for no longer than six (6) months from the start date of IVIG therapy. If there is a change in patient information, a new PPO shall be completed.
17. IVIG shall **NOT** be issued without a valid PPO, even in emergency situations.

18. The clinical outcome evaluation shall accompany the requisition/order for IVIG when required.
19. If therapeutic value is not realized through IVIG therapy, the therapy will be discontinued and alternative treatments must be explored.
20. Serum IgG levels shall be monitored prior to every sixth dose to ensure optimum dosing for primary and secondary immune deficiency conditions.
21. Serum IgG levels, when required, shall be drawn within 24 hours before the next IVIG is given to ensure it is a true trough level.
22. Hospitals shall report their use of IVIG into the Intravenous Immunoglobulin Network (IVIN) database housed at the Nova Scotia Provincial Blood Coordinating Program (NSPBCP).
23. Transfusion reactions associated with IVIG shall be reported to the TML.
24. There shall be no expiry (outdating) of IVIG. Inventory management practices shall be in place that prevent the expiry of these products.
25. In the event of an emergency release of IVIG, the request shall be granted if it meets all the criteria for release. For any future doses, the request shall be reviewed through the normal process.

Guidelines

1. IVIG should only be used when other equally safe and efficacious alternative therapy has failed.
2. “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).
3. Dosing by adjusted body weight improves patient safety by reducing unnecessary exposure to higher doses of IVIG which are associated with greater incidence of adverse events including hemolysis and thrombosis.
4. The IVIG dose calculator only accepts heights that equal or exceed 152.4 centimeters (60 inches). Dosing for these patients should use actual body weight.
5. Patients on chronic IVIG therapy should have dose titrated so that minimal effective dose is prescribed.

6. Regular evaluations are required to ensure that the treatment continues to be effective and appropriate.
7. The recommended target serum IgG level should be maintained between 7-10 g/L for primary and secondary immune deficiency conditions.
8. The clinical outcome evaluation is completed to ensure:
   8.1. IVIG remains of therapeutic value; and
   8.2. The minimal effective dose of IVIG is being prescribed.

Quality Control

1. Transfusion safety officer (TSO) or designated IVIG data submitter shall review all requests for IVIG.
2. All TML staff shall be trained and familiar with the review and approval of IVIG requests. In the absence of TSO or designate, they may issue, if required. The TSO or designate will check review when available.
3. The PBCP shall review all requests that do not meet the Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin (IVIG/SCIG) to ensure request and approval process is consistent with the Common Policy.

Key Words

Common policy, intravenous immunoglobulin, IVIG, PPO, request, approval

Supplemental Materials

1. NLPBCP IVIG dose calculator is available at https://www.health.gov.nl.ca/health/bloodservices/resources/dosage_calculator.html
2. Appendix A - Request/Approval Flowchart
3. Atlantic Ministries of Health Common Policy for Intravenous and Subcutaneous Immunoglobulin
4. Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin (IVIG/SCIG)

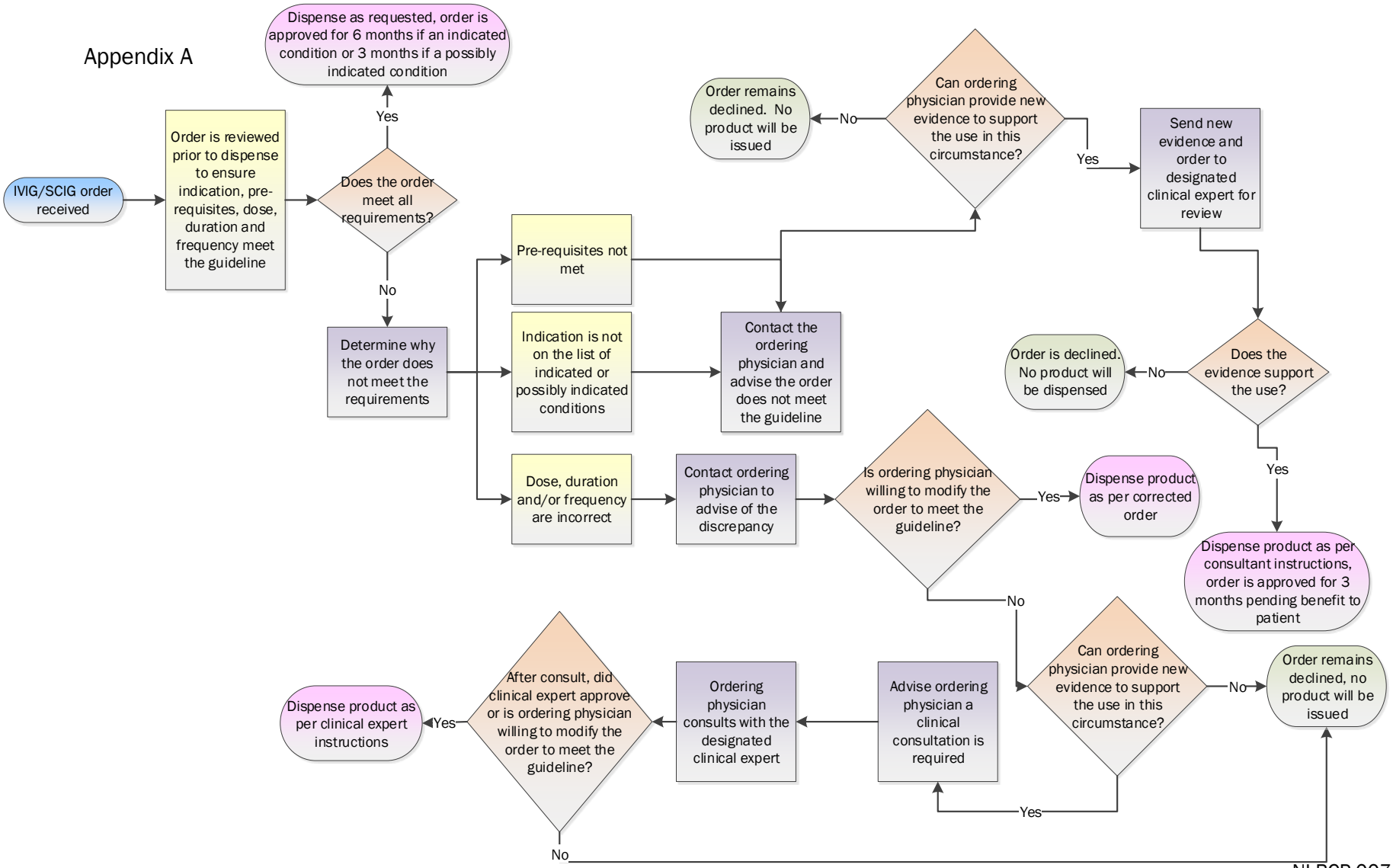
References

Callum, J. L. (2016). *Bloody Easy 4: Blood Transfusions, Blood Alternatives and Blood Transfusion Reactions.* Toronto: Ontario Regional Blood Coordinating Network (ORBCoN).

Canadian Society for Transfusion Medicine. (2017). *Standards for Hospital Transfusion Services.* (Version 4.0). Markham, ON: Author.

Canadian Standards Association. (2015). *Blood and blood components, Z902-15.* Mississauga, ON: Author.

Appendix A


IVIG/SCIG order received
Order is reviewed prior to dispense to ensure indication, pre-requisites, dose, duration and frequency meet the guideline
Does the order meet all requirements?
Yes
Dispense as requested, order is approved for 6 months if an indicated condition or 3 months if a possibly indicated condition
No
Determine why the order does not meet the requirements
Pre-requisites not met
Indication is not on the list of indicated or possibly indicated conditions
Dose, duration and/or frequency are incorrect
Contact the ordering physician and advise the order does not meet the guideline
Contact ordering physician to advise of the discrepancy
Is ordering physician willing to modify the order to meet the guideline?
Yes
Dispense product as per corrected order
No
Can ordering physician provide new evidence to support the use in this circumstance?
No
Order remains declined. No product will be issued
Yes
Send new evidence and order to designated clinical expert for review
Does the evidence support the use?
No
Order is declined. No product will be dispensed
Yes
Dispense product as per consultant instructions, order is approved for 3 months pending benefit to patient
Can ordering physician provide new evidence to support the use in this circumstance?
No
Order remains declined, no product will be issued
Yes
Advise ordering physician a clinical consultation is required
Ordering physician consults with the designated clinical expert
After consult, did clinical expert approve or is ordering physician willing to modify the order to meet the guideline?
Yes
Dispense product as per clinical expert instructions
No