JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTH SYSTEM	Johns Hopkins Health System **JHM Quality and Safety Clinical Practice Manual** **Medication Use Policies**	*Policy Number*	MDUP008
		Effective Date	10/04/2021
	Subject **Immune Globulin Therapy Policy**	*Page*	1 of 6
		Supersedes Date	N/A

This document applies to the following Participating Organizations:

Howard County General Hospital, Inc.	Johns Hopkins All Children's Hospital	Johns Hopkins Bayview Medical Center, Inc.	Sibley Memorial Hospital
Suburban Hospital, Inc.	The Johns Hopkins Hospital		

Keywords: auto-immune, flebogama, gammagard, gamunex c, guillain barre, hizentra, hyperbilirubinemia, IgA, IgG, immune deficiencies, immune globulin, ITP, IVIG, MG, MS, multiple sclerosis, myasthenia gravis, privigen, SQIg, sugar-free, transverse myelitis

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I. PURPOSE

The purpose of this policy is to provide and/or ensure:

1. Best practices for the safe management of patients receiving immune globulin (Ig) therapy.
2. Safe and effective prescribing, handling, and administration of Ig products.
3. Safe and accurate dispensing of Ig products.
4. Comparable level of care for all patients receiving Ig products regardless of patient location.
5. Safe use of infusion pumps for administration of intravenous immune globulin therapy.

II. SCOPE

A. All inpatients and outpatients receiving Immune globulin.

B. This policy does NOT apply to hyperimmune globulin products (e.g., CMVIg, Cytogam, tetanus immune globulin, rabies immune globulin, hepatitis B immune globulin, Rho immune globulin).

1. For use of Rh Immune Globulin, Administration in Obstetric Patients see OBGYN005.

III. POLICY

The Participating Organization shall ensure that the ordered Ig product and dose are appropriate for each patient. Anaphylaxis medications shall be readily available for patients receiving Ig infusions.

IV. DEFINITIONS

Adverse Reaction	The development of undesired side effects or toxicity caused by the administration of drugs which may be immediate or delayed.
Anaphylaxis	A serious or potentially life-threatening allergic or hypersensitivity reaction to an allergenic antigen, mediated by interactions between mast cells and immunoglobulin E (IgE) that produce an antigen-antibody reaction.
Direct Supervision	Oversight exercised by a registered nurse who is present on the unit of care during Ig infusion.
Immune Globulin (Ig)	A group of glycoproteins found in human blood that function as antibodies capable of recognizing and binding to antigens. The Ig found in the largest amount in human blood is IgG.
Intravenous Immune Globulin (IVIg)	A sterile preparation of concentrated antibodies (immune globulins) recovered from human plasma of healthy donors intended for administration as an intravenous infusion (see Appendix A for a list and comparison of selected IVIg products).
Subcutaneous Immune Globulin (SQIg)	A sterile preparation of concentrated antibodies (immune globulins) recovered from human plasma of healthy donors intended for administration as a subcutaneous infusion.

V. RESPONSIBILITY

A. Authorized Prescriber

1. Enter orders utilizing Ig order sets, treatment plans or therapy plans.
    a. Consideration must be given to order the most appropriate immune globulin product for each patient (i.e. prior adverse events or patients who have been stabilized on a particular product).
    b. Orders for Ig products must be calculated according to the patient's dosing weight unless the patient is obese in which case adjusted body weight is utilized. a
        i. Adults: For obese patients (BMI>30) IVIg will be dosed using Adjusted Body Weight [Ideal Body Weight + 0.4 x (Actual Body Weight - Ideal Body Weight)].
        ii. Pediatrics: For patients with a BMI-for-age percentile of greater than or equal to 95, adjusted body weight is used.
    c. All orders are rounded to the nearest vial size.
    d. Assess renal function.
2. Inform patient, parent, or guardian of need for infusion, any preparation necessary, possible adverse reaction, and plan of treatment.
3. Pre-medication is not required, but may be considered, for initial Ig infusions.
4. Anaphylaxis medications should be readily available for patients receiving Ig infusions.
5. Significant infusion reactions must be documented in the allergy section of the EMR.

6. Include the indication for Ig within the order in the event of an Ig shortage.
7. Some vaccines (e.g., live vaccines) may need to be postponed following Ig administration. Refer to the American Academy of Pediatrics Red Book or other vaccine resources for recommendations for vaccine administration after Ig therapy.
8. For patients receiving Ig in an outpatient infusion centers doses of Ig that exceed 80 grams shall be administered on two separate visits. If this limit is to be exceeded, infusion clinic leadership must approve additional chair time.

B. Pharmacy
1. Ensures that the ordered Ig product and dose are appropriate for each patient, in consultation with the authorized prescriber, using supporting references as guidance (see the CMS approved Compendia, e.g., Micromedex®, for information on FDA approved and non-FDA approved uses which can be treated the same as labeled indications from a CMS standpoint).
2. For inpatient orders may round the ordered dose within a 10% range to match currently stocked vial sizes if necessary. If outside of the 10% range, contact authorized prescriber to approve dose change.
3. For inpatient administration of SQIg, communicates with prescriber, nurse, and/or patient regarding the patient's outpatient drug delivery system, ensures from the nurse the presence of supplies for subcutaneous administration, and the plan for administration prior to order verification and drug preparation (see Appendices B, C, D and E).
4. Doses of Ig prepared in a bag or syringe must be prepared using "Epic Dispense Preparation" so that the lot number is captured.

C. Registered Nurse
1. For subcutaneous administration, validates the supplies are present and communicates the presence of supplies to the pharmacist.
   a. At JHH, for adult and pediatric patients, page the "Pediatric Allergy and Immunology Consult Service" if patient does not bring supplies for subcutaneous infusion, as the supplies needed for administration via home infusion pump or manual push are not stocked on nursing units. See Appendices D and E for supplies needed.
   b. At all other sites, inform authorized prescriber that supplies are not present and await further instruction.
2. Monitors patient for adverse reactions related to Ig therapy (refer to Appendix B: Guidelines for Administration of Intravenous (IV) Immune Globulin).
3. Identifies any infusion reactions and notifies the authorized prescriber.

VI. PROCESS

A. **Comparison of Ig Products**
1. For comparison of Ig products, see Appendix A.

B. **IVIg Administration**
1. For intravenous immune globulin administration, see Appendix B.
   a. Use the drug library in the infusion pump for administration of intravenous immune globulin.

C. **IVIg Infusion Algorithm**
1. The infusion algorithm is as follows:
   a. Begin infusion at 0.8 mg/kg/min.
   b. 30 minutes after beginning infusion, if no adverse reaction occurs, increase infusion to 1.7 mg/kg/min.
   c. 60 minutes after beginning infusion, if no adverse reaction occurs, increase infusion to 3.3 mg/kg/min.
   d. 90 minutes after beginning infusion, if no adverse reaction occurs, increase infusion to 8.3 mg/kg/min. Continue at this rate until remaining volume is infused.

D. **Subcutaneous Ig Administration**
1. For guidelines for subcutaneous immune globulin administration, see Appendix C.
   a. For subcutaneous administration via Freedom Pump, see Appendix D.
   b. For subcutaneous administration via manual push, see Appendix E.

i. Subcutaneous administration via manual push is not allowed at JHACH.

E. **Ig Administration in Obstetrical Settings**
   1. For intravenous immune globulin administration in the obstetrical setting, see Appendix F.

F. **Ig Management During a Shortage**
   1. See Appendix G

G. **Reportable Conditions**
   1. The following conditions should be reported to an authorized prescriber:
      a. Signs/symptoms of infusion reactions.
      b. Recorded weight changes of 10% or more from previously documented recorded weight (excluding NICU and obstetrical patients).

H. **Documentation**
   1. Authorized prescriber will document occurrence of infusion reaction.
   2. When administering Ig via vial, will scan vial which will generate a log of the lot number within the EMR.
   3. Pharmacist will record lot numbers for all doses dispensed from pharmacy as described in Section V.B.4.

VII. DISSEMINATION

This policy will be communicated to the appropriate JHHS personnel via the following channels:

1. This policy will be placed in the JHM Quality and Safety Clinical Practice Manual on the HPO multi-entity policy website. In the event of web access difficulty, this policy can be accessed on the downtime computers in clinical areas.

VIII. SUPPORTIVE INFORMATION

See Also:

1. PAS015 Patient Care Equipment and Devices, Appropriate Use, Management and Reporting of....
2. RMS Medical Products http://www.rmsmedicalproducts.com.

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Sponsor:

- Medical Executive Leadership Council

Developer(s):

- JHHS Formulary Management and Medication Use Policy Committee
- JHH Pharmacy and Therapeutics Committee

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Howard County General Hospital, Medical Executive Committee	7/15/21
Sibley Memorial Hospital, Medical Executive Committee	7/13/21
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Johns Hopkins All Children's Hospital, Medical Executive Committee	7/13/21

IX. SIGNATURES

Revision History:

- 10/8/21 - A correction was made in Appendix B to the micron in-line filter.

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