(A) Policy Statement
Intravenous immune globulin dosing at the University of Toledo Medical Center will be based on the patient’s ideal body weight (IBW), actual body weight (ABW) if less than IBW, or dosing weight (DW) if obese. In order to facilitate the ordering process and ensure proper reimbursement, an inpatient iForm will be utilized and an outpatient standardized order form will be utilized for ordering of IVIG. Outpatient administration is the preferred location and should be utilized unless inpatient administration is clinically necessary. Gammagard will be the preferred IVIG formulation in both the inpatient and outpatient setting. Patients with a pre-existing precertification for another agent can continue to receive the same agent. When a new precertification is warranted, Gammagard will be the preferred agent and a new precertification for Gammagard should be obtained. Gammagard will be dispensed unless a DAW is selected for an alternative formulation. Precertification required. If precertification denied, appeal process must include providing supporting primary literature and appeal to P&T chair, Chief Medical Officer, or Medical Chief of Staff for approval of use.

(B) Purpose of Policy
To provide calculations for the determination of IVIG dosing by ideal body weight or dosing weight and the procedure for ordering the drug and to provide proper procedures and indications for the inpatient and outpatient ordering of IVIG.

(C) Procedure
1. Outpatient administration is the preferred location and should be utilized unless inpatient administration is clinically necessary. Pharmacist will intervene on IVIG inpatient orders to see if treatment can be delayed until outpatient setting.
2. Per package insert Gammagard initial and subsequent infusions may be at a concentration of 10%.
3. Precertification required. If precertification denied, appeal process must include providing supporting primary literature and appeal to P&T chair, Chief Medical Officer, or Medical Chief of Staff for approval of use.
4. Orders for IVIG must be for an approved indication. See appendix 1 for inpatient iForm indications and appendix 2 for outpatient indications.
   a. If order is not for an approved indication, physician must provide primary literature for IVIG’s use.
   b. After submission of the primary literature a clinical pharmacist will review for appropriateness.
   c. If denied use by clinical pharmacist, the physician may appeal to the Chair of the P&T department, the Chief of Staff, or the Chief Medical Officer. The decision after appeal is final.
5. Gammagard will be the preferred IVIG formulation and will be dispensed unless a DAW is selected for an alternative formulation.
6. Orders for intravenous immune globulin at the University of Toledo Medical Center should be written for as a mg/kg dose
   a. Upon receiving the order for IVIG, the pharmacist will calculate the patient’s ideal body weight by using the appropriate formula below:
      Male patient > 60 in = 50 + (2.3 * number of inches > 60in)
      Female patient > 60 in = 45.5 + (2.3 * number of inches > 60in)
      If < 60 inches:
      Male patient = 50kg - 0.83kg for each inch less than 60 in
      Female patient = 45.5kg - 0.75kg for each inch less than 60 in
   b. If the patient’s actual body weight (ABW) is 30% above IBW, a dosing weight will be calculated and used based on the following formula:
      \( DW = IBW + 0.4 \times (ABW - IBW) \)
   c. If the patient’s actual body weight is less than the patient’s ideal body weight, the actual body weight will be used to calculate the dose of the drug.
   d. Dose will be rounded to the nearest 5grams
   e. The pharmacist will write the order for IVIG using the appropriate calculation listed above.
      - Outpatients:
        1. orders will be written on physicians order sheet for outpatients
2. the pharmacist will note “per UTMC P&T approved policy”
3. Pharmacist will note prescribing physician
4. Pharmacist signature on order is required
5. Pharmacist will send copy of order through fax scanner to attach to patient profile in pharmacy system and send original copy to nursing unit to be placed in the patient chart.

- Inpatients:
  1. dose will be verified as IBW or DW from the iForm for inpatients
  2. if dose not calculated correctly the pharmacist will re-enter the order from the iForm with the correct dose and discontinue the previous order.
  3. Pharmacy will add to comments in HEO “per UTMC P&T approved policy”

7. Inpatient Process:
   i. Steps for pharmacist review of IVIG order
      1. Physician enters IVIG in HEO
      2. Pharmacist receives IVIG order in HMM
      3. Can IVIG use be delayed to outpatient?
         Yes  Contact prescribing MD and intervene
         No
      4. Is the IVIG ordered for an indication listed on the iForm?
         Yes
         5. For an indication listed on the iForm: proceed to the following RPh verification steps
         6. For indications of “other”: ask MD for primary literature (with dosing) to justify use. Use will be evaluated by a clinical pharmacist for approval. If denied, will approval by P&T Chair, Chief Medical Officer, or Medical Chief of Staff for administration
         7. If use is justified proceed to steps 8-10
         8. Verify that the formulation is Octagam (unless DAW written for another formulation)
         9. Verify that the dose ordered corresponds to the recommended dosing for indication (as listed on iForm) and is calculated based on IBW (unless actual BW<IBW) rounded to the nearest 5 grams
         10. Verify that the order contains instructions for infusion rate (max of 4 mL/kg/hr; unless risk for renal dysfunction/VTE, then max of 2 mL/kg/hr).

8. Outpatient Process:
1. Physician faxes IVIG order

2. Pharmacist places IVIG on approved IVIG order form

3. Is the IVIG ordered for an indication listed on the order form?
   Yes
   5. For an indication listed on the order form: proceed to the following RPh verification steps
   8. Verify that the formulation is Octagam (unless DAW written for another formulation)
   9. Verify that the dose ordered corresponds to the recommended dosing for indication (as listed on order form) and is calculated based on IBW (unless actual BW<IBW) rounded to the nearest 5 grams
   10. Verify that the order contains instructions for infusion rate (max of 4 mL/kg/hr; unless risk for renal dysfunction/VTE, then max of 2 mL/kg/hr).
   No
   6. For indications of “other”: ask MD for primary literature (with dosing) to justify use. Use will be evaluated by a clinical pharmacist for approval. If denied, will approval by P&T Chair, Chief Medical Officer, or Medical Chief of Staff for administration
   7. If use is justified proceed to steps 8-10

Approved by:
Russell Smith Pharm D, BCPS
Director of Pharmacy

Dan Barbee RN, MBA
Chief Executive Officer

Review/Revision Date:
8/15
10/17

Next Review Date: 10/1/2020

Policies Superseded by This Policy:
It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.

Appendix 1: Inpatient Intravenous Immunoglobulin (IVIG) iForm:
- Outpatient use of IVIG is encouraged unless patient’s clinical condition warrants inpatient administration of IVIG.
- At UTMC, the preferred IVIG preparation for administration is Gammagard®.
• Ideal body weight will be used unless actual body weight is less than ideal body weight
• iForm will automatically pull in last known height and weight
• Physician will select the appropriate indication which will have the recommended dosing
• Physician will select the desired gm/kg of IVIG for the patient based on indication
  o iForm will automatically calculate the appropriate dose per UTMC policy
• If an unapproved indication the physician will have to provide primary literature for IVIG’s use.
• Literature will be reviewed by a clinical pharmacist for approval
• If denied by clinical pharmacist the physician can appeal to the Chair of P&T, Chief Medical Officer, Or Medical
  Chief of Staff. The appeal decision is final.
• Pharmacist will review the order for appropriate indication and dose
• Baseline labs include: basic metabolic panel and IgA level

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary immunodeficiency diseases</td>
<td>0.4-0.6 g/kg every 3-4 weeks</td>
</tr>
<tr>
<td>Idiopathic thrombocytopenic purpura</td>
<td>0.4 g/kg/d x5 days or 1-2 g/kg/d x1-2 days</td>
</tr>
<tr>
<td>Dermatomyositis and polymyositis</td>
<td>2 g/kg divided doses every 4 weeks</td>
</tr>
<tr>
<td>Vasculitis</td>
<td>0.4 g/kg/d x5 days</td>
</tr>
<tr>
<td>Guillain-Barre syndrome</td>
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</tr>
<tr>
<td>Chronic demyelinating polyneuropathy</td>
<td>LD: 2 gm/kg divided over 2-4 days</td>
</tr>
<tr>
<td></td>
<td>MD: 1 gm/kg every 3 weeks</td>
</tr>
<tr>
<td>Multifocal motor neuropathy</td>
<td>0.5-2.4 g/kg/month</td>
</tr>
<tr>
<td>Lambert-Eaton myasthenic syndrome</td>
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</tr>
<tr>
<td>Myasthenia gravis</td>
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</tr>
<tr>
<td>Stiff-man syndrome</td>
<td>2 g/kg divided over several days</td>
</tr>
<tr>
<td>Autoimmune mucocutaneous blistering skin diseases</td>
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</tr>
<tr>
<td>Pediatric HIV infection</td>
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<td>Kawasaki disease</td>
<td>1-2 g/kg over 10-12 hours</td>
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<tr>
<td>Hypogammaglobulinemia with recurrent bacterial infection</td>
<td>0.4-0.6 g/kg every 3-4 weeks</td>
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<tr>
<td>B-cell chronic lymphocytic leukemia</td>
<td>0.4-0.6 g/kg every 3-4 weeks</td>
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<tr>
<td>Bone marrow transplantation</td>
<td>0.5 g/kg/week</td>
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<td>Antibody-mediated rejection/desensitization prior to transplantation</td>
<td>Up to 2 g/kg/d x2-3 doses or 0.1-0.5 gm/kg/dose every other day with plasmapheresis</td>
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<tr>
<td>CMV-induced pneumonitis in solid organ transplant</td>
<td>0.5 g/kg x5 days</td>
</tr>
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</table>

*Other (please describe): ________________________________
*Must provide supporting literature to the pharmacist for the desired indication

Height: automatically entered    Weight: automatically entered

Gammagard must enter value mg/kg; total dose: automatically calculated (round to the nearest 5 gram)
• Use ideal body weight for all patients. If actual body weight is less than ideal body weight, use the actual body weight.

Gammagard __mL/kg/hr IV infusion
• Initiate at rate of 0.5 mL/kg/hr and titrate every 30 minutes to a maximum rate of 4 mL/kg/hr.
Appendix 2: **Outpatient Intravenous Immunoglobulin (IVIG) Order Form**

- Precertification/prior authorization must be approved before use and faxed to pharmacist at ext. 6066
  - If precertification/prior authorization is denied, use must be approved by Chair of P&T, Chief Medical Officer, Or Medical Chief of Staff in writing and faxed to pharmacy at ext. 6066
- Per UTMC policy: ideal body weight will be used unless actual body weight is less than ideal body weight
- P&T approved dosing and indications provided, must provide total dose and mg/kg dose
- If an unapproved indication the physician will have to provide primary literature for IVIG’s use.
- Literature will be reviewed by a clinical pharmacist for approval
- If denied by clinical pharmacist the physician can appeal to the Chair of P&T, Chief Medical Officer, Or Medical Chief of Staff. The appeal decision is final.
- Baseline lab suggestions: basic metabolic panel and IgA level

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*Other:
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| Height: _____ | Weight: _____ |

**IVIG** __mg/kg; total dose: ____ (round to the nearest 5 gram)
- Use ideal body weight for all patients. If actual body weight is less than ideal body weight, use the actual body weight.

**IVIG** __mL/kg/hr IV infusion
- Initiate at rate of 0.5 mL/kg/hr and titrate every 30 minutes to a maximum rate of 4 mL/kg/hr.
- If at risk for renal dysfunction or thromboembolism: maximum rate is 2 mL/kg/hr.