Intravenous Immune Globulin Toolkit for Ontario

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Copies of these documents can be downloaded from [www.transfusionontario.org](http://www.transfusionontario.org).

The Ontario Regional Blood Coordinating Network acknowledges with sincere appreciation the funding support of the Ministry of Health and Long-Term Care to continue our work.
Introduction

In 2006, the Blood Programs Coordinating Office (BPCO) in Ontario launched a new blood programs initiative, the Ontario Regional Blood Coordinating Network (ORBCoN). This network was mandated to engage Ontario hospitals with transfusion services by setting up educational and communication opportunities, and to support hospitals with utilization improvement and inventory management tools. One of the many projects undertaken by ORBCoN was an IVIG utilization management initiative.

Intravenous Immune Globulin (IVIG) is a product prepared by several commercial manufacturers who use plasma derived from donors to extract immunoglobulin subclass gamma (IgG). IVIG is commonly used to treat patients for a number of labeled and unlabeled indications.

IVIG use has risen dramatically across Canada since its development, exceeding a 10% increase in some years. Over the past five years, Ontario’s IVIG utilization and expenditures have risen to 1.56 million units at a cost of $97.9 million in 2010/11, representing an increase of 44% in the number of units and a 53% increase in costs.

The toolkit was originally launched in September 2010 with the purpose to:
- Provide guidelines for appropriate use of Intravenous Immune Globulin
- Provide health care practitioners involved in the infusion of IVIG with best practice information

The toolkit contained the following documents, some of which have been revised for this release:
- Ontario IVIG Utilization Management Guidelines version 2.0 March 31, 2012 (version 1.0 was dated September 2010)
- MOHLTC IVIG Request Form version 2.0 March 31, 2012 (version 1.0 IVIG Request form was dated September 2010)
- Implementing a Dose Calculator Information for Treating Physicians version 2.0 March 31, 2012 (version 1.0 was dated September 1, 2010).
- Standard Infusion Guidelines and Adverse Events Chart for IVIG Infusion version 1.0 September 1, 2010
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For more information relating to specific brands of IVIG available please refer to the following Canadian Blood Services document “Immune Globulin Comparison table”. The current version can be found on the CBS website www.blood.ca under Hospitals and Physicians tab, Plasma Protein Products, Product Comparison tables section.
Ontario
Intravenous
Immune Globulin (IVIG)
Utilization Management Strategy

Prepared by:
Ministry of Health and Long-Term Care
Ontario Regional Blood Coordinating Network
Ontario IVIG Advisory Panel

March 31, 2012
Overview

In its recently released Action Plan for Health Care, the Ontario government cites the need for our health care partners to help transform the system through the effective use of evidence-based treatments, diagnostics and medications. The goal of the plan is to improve patient care by gaining better value from our health care system.

With this in mind, the ministry asks all of our health care partners to review this communication and to ensure that Intravenous Immune Globulin (IVIG) in Ontario hospitals is used only where evidence suggests that this treatment is the most effective means of care.

In 2007, an audit of IVIG utilization was conducted by the Ontario Regional Blood Coordinating Network (ORBCoN). The three-month audit involved 25 hospitals across the province representing about 66% of IVIG use in Ontario for that time period. The audit included 1,345 patients, 4,234 infusions, and approximately 200,000 grams of IVIG and produced the following results:

- 50% of use was for licensed clinical indications
- 40% of use was for unlicensed, potentially indicated clinical indications
- 10% of use was for unlicensed, not indicated clinical indications

To limit use to indications with evidence of clinical efficacy, with appropriate dosages and frequencies, ORBCoN and the Ontario IVIG Advisory Panel (IVIGAP) developed the Ontario IVIG Utilization Management Guidelines and Toolkit, which were disseminated to Ontario hospitals in November 2009 and September 2010 respectively. The Toolkit included a Standard IVIG Request Form; IVIG Dose Calculator; Standard Infusion Guidelines; and Adverse Events Chart.

Based on an ORBCoN survey in January 2011, only 23% (29/128) of IVIG user hospitals had implemented the Guidelines, and 20% (26/128) had implemented the Request Form.

To increase adoption of the Ontario IVIG Utilization Management Guidelines and Toolkit, in an effort to mitigate the continued unsustainable increases in IVIG utilization, the Ministry of Health and Long-Term Care (MOHLTC), in partnership with ORBCoN and the Ontario IVIG Advisory Panel, will be implementing the IVIG Utilization Management Strategy. The IVIG Strategy includes the following directives:

1. Adherence to Ontario IVIG Utilization Management Guidelines (v2.0-March 2012)
2. Implementation of the MOHLTC IVIG Request Form
3. Review/Approval for Indications Not Listed on the MOHLTC IVIG Request Form
4. Dosing Through “Adjusted Body Weight” Calculation
5. Evaluating Clinical Outcomes and Need for Reassessment
6. No Outdating of Product
7. Provincial IVIG Utilization Audit in September 2012

While this is the first formal communication from the ministry, we acknowledge all documentation relating to IVIG that has been previously issued by ORBCoN. The ministry would also like to take this opportunity to thank ORBCoN and the IVIGAP for their valuable time and expertise in the development of the IVIG Guidelines, Toolkit and Strategy.

All resources referenced in this document are available at [www.transfusionontario.org](http://www.transfusionontario.org).
Background

IVIG is a plasma-derived product that contains antibodies that contribute to immunity from a range of diseases. In fact, a literature search revealed 80 to 100 recognized clinical indications.

IVIG use has risen dramatically across Canada since its development. Over the past five years, Ontario’s IVIG utilization and expenditures have risen to 1.56 million units at a cost of $97.9 million in 2010/11, representing an increase of 44% in the number of units and a 53% increase in costs. IVIG is priced at $55-75 per gram and can cost about $15,000 – $250,000 per patient, per year, depending on the amount given per treatment; and frequency of treatments.

The Canadian Blood Services (CBS) provides IVIG to hospitals for patient use. Hospitals place their order with CBS and CBS ships to them at no charge. Provinces and Territories (except Quebec) directly fund CBS for the blood and blood products shipped to their respective jurisdiction, so the products are often regarded as “free” to end users (hospitals) who do not need to account for the cost in their budgets.

Making the product available for patients with medical conditions where there is evidence of clinical efficacy is a primary objective of the IVIG Strategy. Given the growth in the utilization for “potentially indicated” clinical indications, supply may not be able to meet demand without control points in place. The overall impact on the supply from a new use (e.g. Alzheimer’s disease), left uncontrolled, could limit accessibility due to diminishing supply.

In 2006, the ministry identified the unsustainable increases in IVIG utilization as a key priority with concurrence from the Ontario Blood Advisory Committee. Consequently, ORBCoN, a program funded by the MOHLTC, established the IVIG Advisory Panel. The 2007 provincial IVIG audit, managed by ORBCoN, found that IVIG was used for over 80 different clinical indications – many of which are not supported by randomized clinical trials. This led to the development of the Ontario IVIG Guidelines and Toolkit.

The Canadian National Advisory Committee on Blood and Blood Products (NAC) developed national guidelines for the use of IVIG in Hematology (2007), Neurology (2007), Immunology (2010) and Solid Organ Transplantation (2010). The IVIG Advisory Panel prepared the Ontario IVIG Guidelines based on the NAC guidelines, results from the 2007 audit, and from other jurisdictions where IVIG utilization guidelines are in place (British Columbia, United Kingdom and Australia).

Scope

The IVIG Utilization Management Strategy applies to all hospitals where IVIG is dispensed, whether the product is handled by Transfusion Services or by Pharmacy Services. Furthermore, it is vital that physicians who order IVIG are made aware of and adhere to these directives.
Ontario IVIG Utilization Management Strategy
For Implementation In Ontario Hospitals In 2012/13

1. Adherence to Ontario IVIG Utilization Management Guidelines
version 2.0 March 2012

The clinical indication, dose and duration of therapy must be in accordance with the Ontario IVIG Utilization Management Guidelines. The list of recommended indications is as follows:

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hematology</td>
<td>1.1. Fetal Neonatal Alloimmune Thrombocytopenia</td>
</tr>
<tr>
<td></td>
<td>1.2. Hemolytic Disease of the Fetus and Newborn</td>
</tr>
<tr>
<td></td>
<td>1.3. Idiopathic Thrombocytopenic Purpura Adult*</td>
</tr>
<tr>
<td></td>
<td>1.4. Idiopathic Thrombocytopenic Purpura Pediatric*</td>
</tr>
<tr>
<td></td>
<td>1.5. Post Transfusion Purpura</td>
</tr>
<tr>
<td>2. Neurology</td>
<td>2.1. Chronic Inflammatory Demyelinating Polyneuropathy*</td>
</tr>
<tr>
<td></td>
<td>2.2. Guillain-Barre Syndrome</td>
</tr>
<tr>
<td></td>
<td>2.3. Multifocal Motor Neuropathy</td>
</tr>
<tr>
<td></td>
<td>2.4. Myasthenia Gravis</td>
</tr>
<tr>
<td>3. Dermatology</td>
<td>3.1. Dermatomyositis</td>
</tr>
<tr>
<td></td>
<td>3.2. Pemphigus Vulgaris and Variants</td>
</tr>
<tr>
<td>4. Rheumatology</td>
<td>4.1. Juvenile Dermatomyositis</td>
</tr>
<tr>
<td></td>
<td>4.2. Kawasaki Disease</td>
</tr>
<tr>
<td>5. Infectious Diseases</td>
<td>5.1. Staphylococcal toxic shock</td>
</tr>
<tr>
<td></td>
<td>5.2. Invasive Group A streptococcal fasciitis with associated toxic shock</td>
</tr>
<tr>
<td>6. Immunology</td>
<td>6.1. Primary Immune Deficiency*</td>
</tr>
<tr>
<td></td>
<td>6.2. Secondary Immune Deficiency*</td>
</tr>
<tr>
<td></td>
<td>6.3. High risk allogeneic stem cell transplantation</td>
</tr>
<tr>
<td>7. Solid Organ Transplant</td>
<td>7.1. Acute antibody mediated rejection</td>
</tr>
<tr>
<td></td>
<td>7.2. Kidney transplant from living donor</td>
</tr>
</tbody>
</table>

*Licensed by Health Canada. Refer to Ontario IVIG Guidelines for other indications and a list of references.

Health Canada has licensed IVIG for use in the following indications:
1. Idiopathic Thrombocytopenic Purpura
2. Chronic Inflammatory Demyelinating Polyradiculoneuropathy
3. Primary Immune Deficiency
4. Secondary Immune Deficiency
   * B-cell Chronic Lymphocytic Leukemia
2. Implementation of the MOHLTC IVIG Request Form

All new requests for IVIG must be ordered using the MOHLTC IVIG Request Form, whether the product is handled through the Transfusion Service or through the Pharmacy. This will ensure that the request is in accordance with the provincial Guidelines and that any specific prerequisites have been addressed.

- Hospitals that have already implemented an IVIG Request Form will need to adopt the MOHLTC March 2012 version.
- Modification of the Request Form is not permitted. This will prevent the addition of indications not on the Guidelines and allow for standardized data collection.
- A record of completed Request Forms must be kept for five (5) years to allow for spot audits to measure compliance with the IVIG Strategy. The record can be paper based, electronic, or microfilm.
- The MOHLTC IVIG Request Form must be implemented by June 30, 2012.

Implementation of the Form will facilitate the provincial IVIG utilization audit scheduled for September 2012. See Appendix A for the MOHLTC IVIG Request Form and instructions for use.

3. Review/Approval for Indications Not Listed on Request Form

IVIG ordered for clinical indications not listed on the MOHLTC IVIG Request Form will be subject to screening at the hospital level.

- IVIG user hospitals must select the appropriate physician/committee to review/approve requests for indications not listed on the Form.
- The physician appointed to serve as the approving physician, or their designate, must sign the Form.
- On the Request Form, under the heading 'Other' the non-licensed clinical indication must be entered. See Appendix A for detailed instructions.

**NOTE:** In the event of a life-threatening situation, the request for IVIG will be filled immediately.

Reference information on IVIG use is also available in *Bloody Easy 3: Blood Transfusions, Blood Alternatives and Transfusion Reactions - A Guide to Transfusion Medicine.* In that publication, the following clinical indications are listed as not recommended, not indicated, or ineffective.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Efficacy/Comment</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatoid Arthritis</td>
<td>Ineffective</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Inclusion Body Myositis</td>
<td>Ineffective</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Chronic Fatigue Syndrome</td>
<td>Ineffective</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Recurrent Spontaneous Abortion</td>
<td>Ineffective</td>
<td>Not indicated</td>
</tr>
<tr>
<td>In Vitro Fertilization/Implantation Procedures</td>
<td>Ineffective</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Sepsis In Critical Care Patients</td>
<td>No large randomized controlled trials to confirm benefit</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Autologous Bone Marrow/Stem Cell Transplant</td>
<td>No benefit</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>Ineffective</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Amyotrophic Lateral Sclerosis</td>
<td>Ineffective</td>
<td>Not indicated</td>
</tr>
</tbody>
</table>
4. Dosing Through “Adjusted Body Weight” Calculation

Institutions are required to introduce a strategy to determine the lowest possible dose that maintains clinical efficacy. This is particularly important given that adverse reactions, like hemolysis, are substantially more likely to happen when a high dose of IVIG is infused.

“Ideal body weight” dosing or “adjusted 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 this approach, overweight and obese patients receive a lower dose of IVIG than they would if doses were provided according to their actual body weight. Actual body weight will be used to determine dose for patients weighing ideal or less than ideal body weight. Note that it is acceptable to prescribe lower than the calculated dose.

An **IVIG Dose Calculator**, based on adjusted body weight, is available to easily determine the appropriate dose for all patients. The IVIG Dose Calculator is available in application format for Blackberry and I-system hand-held devices and can be found at [www.transfusionontario.org](http://www.transfusionontario.org).

Use of the IVIG Dose Calculator:

- requires patient height and weight be recorded;
- ensures no errors are made in dosage calculations done manually;
- calculates and adjusts the dose for overweight and obese patients;
- calculates the dose for ideal or less than ideal body weight patients;
- rounds the dose to the closest vial size for all calculations, making dose adjustments required in the Transfusion Service or Pharmacy infrequent; and
- improves patient safety by reducing unnecessary exposure to higher doses of IVIG that are associated with more adverse events.

Note: Institutions who do not adopt the IVIG Dose Calculator tool are required to enact an alternative strategy for adjusting the dose for overweight and obese patients.

5. Evaluating Clinical Outcomes and Need for Reassessment

For patients who are being treated regularly over a period of time, a mechanism to evaluate clinical impact must be established.

- Six months after the initial prescription, the patient should be evaluated to assess therapeutic value and minimal effective dose.
- Every 12 months after that, the patient should again be assessed.
- A new MOHLTC IVIG Request form should be completed for patients when physicians complete a 6 or 12 month clinical impact evaluation and re-initiate IVIG therapy.

This will ensure that IVIG continues to be of therapeutic value; and that the minimal effective dose of IVIG is being prescribed. If therapeutic value is not realized through IVIG therapy, alternative treatments should be explored. This is especially true for any patients receiving the product on a long-term basis.
6. **No Outdating of Product**

There must be no expiry of IVIG. This product has a shelf-life of over two years. Canadian Blood Services does not accept product returns.

- In the event that an over-supply exists in a hospital Transfusion or Pharmacy Service, the product should be re-directed to another facility that can use the product before expiry.
- Hospital staff should contact ORBCoN if they have product nearing expiry and are unsure where to re-direct the product.

7. **Provincial IVIG Utilization Audit in September 2012**

A three-month provincial audit of IVIG use will take place in September 2012. Participation by selected Ontario IVIG user hospitals will be mandatory. Details of the 2012 IVIG Utilization Audit and the list of selected hospitals will be provided closer to the date of the audit.

Implementation of the MOHTLC Request Form will facilitate data collection for the audit process.

The purpose of the 2012 IVIG Utilization Audit is to:

- provide a current snapshot of IVIG use in Ontario;
- indicate any changes in use from the 2007 audit including indications and dosing patterns;
- identify any problem areas to better target future strategies; and
- measure compliance with the IVIG Utilization Management Strategy.

The 2012 Audit will be managed by ORBCoN with support and analysis from the Ontario IVIG Advisory Panel. The final report of the audit results will be submitted to the ministry.
MOHLTC IVIG Request Form

Date Requested: (YYYY/MM/DD) | Date Required: (YYYY/MM/DD)
---|---
Patient weight: ___________ kg | Patient height: ___________ cm
Treating Physician: | Physician Specialty:

Indicate dosage required and duration of therapy

<table>
<thead>
<tr>
<th>Total dose:</th>
<th>g*</th>
</tr>
</thead>
<tbody>
<tr>
<td>___________ g per day X</td>
<td>________ days, q</td>
</tr>
</tbody>
</table>

☐ Dose calculator used.

*Verification of dosage using Dose Calculator tool is recommended. Refer to [http://www.transfusionontario.org/dose/](http://www.transfusionontario.org/dose/)

Duration of therapy:

☐ Single use
☐ ___ treatments (maximum 6, then new approval form required - exception immunology, maximum 12)

IgG level/Platelet Count/other relevant test results.

Result: | Date: |
|---|---|

Clinical Indication for use must be recorded below

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Medical Condition</th>
<th>Suggested dose and duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology</td>
<td>☐ Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)</td>
<td>Maternal dose: weekly 1 g/kg. Infant: an initial dose of 1 g/kg.</td>
</tr>
<tr>
<td></td>
<td>☐ Hemolytic Disease of the Fetus and Newborn (HDFN)</td>
<td>0.5 g/kg over 2 hours; if necessary repeat in 12 hours.</td>
</tr>
<tr>
<td></td>
<td>☐ Idiopathic Thrombocytopenia Purpura (ITP) Adult</td>
<td>Adult: Acute ITP with bleeding or no response to steroids: 1 g/kg daily for 2 days. Chronic ITP Post splenectomy 0.5 g/kg every 4 weeks. Pediatric: One dose of 0.8 to 1.0 g/kg with a second dose given within 48 hours if the platelet count has not increased to &gt;20x10⁹/L.</td>
</tr>
<tr>
<td></td>
<td>☐ Idiopathic Thrombocytopenia Purpura (ITP) Pediatric</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Post-transfusion Purpura</td>
<td>1 g/kg for 2 days.</td>
</tr>
<tr>
<td>Neurology</td>
<td>☐ Guillain–Barré Syndrome (GBS) including Miller-Fisher Syndrome and other variants</td>
<td>Adult: Total dose of 2 g/kg divided over 2 to 5 days. Pediatric: Total dose of 2 g/kg divided over 2 days.</td>
</tr>
<tr>
<td></td>
<td>☐ Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)</td>
<td>Total dose of 2 g/kg divided over 2 to 5 days.</td>
</tr>
<tr>
<td></td>
<td>☐ Multifocal Motor Neuropathy (MMN) initial treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Myasthenia Gravis (MG) initial treatment</td>
<td></td>
</tr>
<tr>
<td>Dermatology</td>
<td>☐ Dermatomyositis</td>
<td>Adult: Total dose of 2 g/kg divided over 2 to 5 days. Pediatric: Total dose of 2 g/kg divided over 2 days.</td>
</tr>
<tr>
<td></td>
<td>☐ Pemphigus Vulgaris and variants</td>
<td>Total dose of 2 g/kg divided over 2 to 5 days.</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>☐ Juvenile Dermatomyositis (JD) initial treatment</td>
<td>Total dose of 2 g/kg divided over 2 days.</td>
</tr>
<tr>
<td></td>
<td>☐ Kawasaki Disease (KD) initial treatment</td>
<td>2 g/kg x 1 day.</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>☐ Staphylococcal Toxic Shock</td>
<td>1 g/kg on day one and 0.5 g/kg per day on days 2 and 3 OR 0.15 g/kg per day for 5 days.</td>
</tr>
<tr>
<td></td>
<td>☐ Invasive Group A streptococcal fascitis with associated toxic shock</td>
<td></td>
</tr>
<tr>
<td>Immunology</td>
<td>☐ Primary Immune Deficiency (PID)</td>
<td>Adult: 0.4-0.6 g/kg once every 4 weeks or SCIG 0.1-0.5 g/kg/week Pediatric: 0.3-0.6 g/kg once every 4 weeks.</td>
</tr>
<tr>
<td></td>
<td>☐ Secondary Immune Deficiency (SID)</td>
<td>Primary Diagnosis:</td>
</tr>
<tr>
<td></td>
<td>☐ Hematopoietic Stem Cell Transplant in primary immunodeficiencies</td>
<td>0.4-0.6 g/kg once every 4 weeks; requirements may increase and should be based on clinical outcome.</td>
</tr>
<tr>
<td>Solid Organ Transplant</td>
<td>☐ Acute antibody mediated rejection</td>
<td>0.1 g/kg/treatment day, or as a set dose of 2 g/kg total.</td>
</tr>
<tr>
<td></td>
<td>☐ Kidney transplant from living donor (recipient sensitization)</td>
<td>2 g/kg/month for 4 months.</td>
</tr>
</tbody>
</table>

Other** Requires Approval

**For Transfusion Medicine or Pharmacy use only

☐ Approved
☐ Denied

Signature of Approving Physician: | Date: |
☐ Dose verified | ☐ Dose adjusted to: | By: |
☐ Confirmed with ordering physician | Date: |

Please fax/send to Transfusion Medicine or Pharmacy

Version 2.0 March 31, 2012
Use of the MOHLTC Intravenous Immune Globulin Request Form

Conditions

This form is to be used for all IVIG requests.

Where a request includes multiple infusions of IVIG (e.g. a course of treatment rather than a single infusion), completing the form once is sufficient, until:

a) Dose is modified, or
b) Six months have lapsed since the initial treatment was prescribed (all conditions except Primary Immune Deficiency), or
c) Twelve months have elapsed since the initial treatment for Primary Immune Deficiency.

Completing the Form

Treating Physician or Designate

1. Complete the date requested and the date required using format YYYY MM DD.
3. Identify treating physician and their specialty e.g. Hematology, Dermatology etc.
4. Identify the total dose per treatment using the dose calculator.*
5. Record IVIG dose and duration of therapy.
6. Check the “dose calculator used” box if dose was confirmed using the dose calculator tool.
7. Check the appropriate box to indicate the clinical indication explaining the request (e.g. check box beside Chronic Inflammatory Demyelinating Polyneuropathy.
8. Check ‘Other’ if the clinical indication does not appear on the list; requests for ‘Other’ indications are subject to screening.
9. Document the platelet count in ITP, IgG level in PID and SID or other relevant test results as required.
10. Evaluate the clinical outcomes of patients to ensure the treatment continues to be effective and appropriate.

Health care professional receiving the request (e.g. laboratory technologist, pharmacy personnel)

1. Verify that the clinical indication coincides with one of the clinical indications listed. If not, proceed to step 4.
2. Verify the dose requested using the dose calculator.
3. Doses that require adjustment must be confirmed with the treating physician and documented on the bottom of the request form.
4. Requests listing ‘Other’ as the clinical indication should be referred to an approving physician for screening.

Approving Physician or Designate

1. Screening of all IVIG requests for clinical indications listed under ‘Other’ is expected.
2. Document whether the request is approved or denied using the shaded area at the bottom of the request form including a signature, date and checking the appropriate box.

Supplementary Information

IVIG will always be provided in life-threatening situations.

Hemolytic reactions due to anti-A and/or anti-B in IVIG have been noted.

Patient should be monitored for signs of hemolysis.

CBC, Blood Group and Antibody Screen should be ordered prior to initial infusion.

In Group A, B or AB patients, within 1 week of initial infusion the following tests are recommended:

CBC, Direct Antiglobulin Test, total and direct bilirubin, retic, LDH, and haptoglobin

*Institutions that do not adopt the dose calculator tool are required to enact an alternative strategy for adjusting the dose for overweight and obese patients.
APPENDIX B
IVIG Advisory Panel Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Specialty</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Lois Shepherd, <em>Chair</em></td>
<td>Hematopathologist, <em>Chair</em></td>
<td>Kingston General Hospital</td>
</tr>
<tr>
<td>Dr. Yulia Lin, <em>Vice-Chair</em></td>
<td>Hematology &amp; Transfusion Medicine, <em>Vice Chair</em></td>
<td>Sunnybrook Health Sciences Centre</td>
</tr>
<tr>
<td>Dr. Jeannie Callum</td>
<td>Director, Transfusion Medicine</td>
<td>Sunnybrook Health Sciences Centre</td>
</tr>
<tr>
<td>Ms. Julie Ditomasso</td>
<td>Transfusion Safety Officer</td>
<td>Hamilton Health Sciences and St. Joseph's Hamilton</td>
</tr>
<tr>
<td>Ms. Kathleen Eckert</td>
<td>Transfusion Safety Officer</td>
<td>London Health Sciences; St. Joseph's London</td>
</tr>
<tr>
<td>Ms. Kate Gagliardi</td>
<td>Regional Blood Coordinator</td>
<td>Ontario Regional Blood Coordinating Network</td>
</tr>
<tr>
<td>Dr. Anthony Giulivi</td>
<td>Transfusion Medicine Director</td>
<td>The Ottawa Hospital</td>
</tr>
<tr>
<td>Ms. Nancy Heddle</td>
<td>Director, McMaster Transfusion Research Program</td>
<td>McMaster University</td>
</tr>
<tr>
<td>Ms. Elenore Kingsbury</td>
<td>Manager, Customer Support &amp; Product Distribution</td>
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</tr>
<tr>
<td>Ms. Debbie Lauzon</td>
<td>Regional Blood Coordinator</td>
<td>Ontario Regional Blood Coordinating Network</td>
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</tr>
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<td>Ms. Wendy Owens</td>
<td>Regional Blood Coordinator</td>
<td>Ontario Regional Blood Coordinating Network</td>
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<tr>
<td>Dr. Elianna Saidenberg</td>
<td>Hematologist</td>
<td>The Ottawa Hospital</td>
</tr>
<tr>
<td>Dr. Kathryn Webert</td>
<td>Director of Operations, Transfusion Medicine</td>
<td>McMaster University Hamilton Health Sciences</td>
</tr>
<tr>
<td>Ms. Laurie Young</td>
<td>Regional Field Officer</td>
<td>Ontario Regional Blood Coordinating Network</td>
</tr>
</tbody>
</table>
Abbreviations and Definitions

Abbreviations

BTL  Blood Transfusion Laboratory
BPCO  Blood Programs Coordinating Office
CBC  Complete blood count
CIDP  Chronic Inflammatory Demyelinating Polyneuropathy
F/NAIT  Fetal Neonatal Alloimmune Thrombocytopenia
GBS  Guillain–Barré Syndrome
HBV  Hepatitis B virus
HCV  Hepatitis C virus
HDFN  Hemolytic Disease of the Fetus and Newborn
HIT  Heparin Induced Thrombocytopenia
HIV  Human Immunodeficiency Virus
HTR  Hemolytic Transfusion Reaction
IgG  Immunoglobulin G
ITP  Immune Thrombocytopenia Purpura
IVIG  Intravenous Immune Globulin
JD  Juvenile Dermatomyositis
KD  Kawasaki Disease
MG  Myasthenia Gravis
MMN  Multifocal Motor Neuropathy
ORBCoN  Ontario Regional Blood Coordinating Network
PANDAS  Pediatric Autoimmune Neuropsychiatric Disorders with Streptococcal Infections
PID  Primary Immune Deficiency
PTP  Post Transfusion Purpura
SCIG  Subcutaneous Immune Globulin
SID  Secondary Immune Deficiency
TTISS  Transfusion Transmitted Injuries Surveillance System
TTP  Thrombotic Thrombocytopenic Purpura
VAHS  Virus Associated Hemophagocytic Syndrome
VCJD  Variant Creutzfeldt-Jakob disease

Definitions

Adverse events  An undesirable and unintended occurrence during or after the administration of whole blood, blood components, or blood products, whether or not considered to be related to the administration of the blood, blood component, or blood product
Dyspnea  Difficult or labored respiration
Pharyngitis  Sore throat caused by inflammation of the back of the throat
Photophobia  An abnormal sensitivity to, and discomfort from, light
Prion  A disease-causing agent that is neither bacterial nor fungal nor viral and contains no genetic material
Urticaria  Hives; skin that erupts into red welts, often with severe itching
IVIG Utilization Management Guidelines and IVIG Strategy

On November 11, 2009, physicians in charge of Blood Transfusion Services and contact personnel in Transfusion laboratories received Version 1.0 of the Ontario Intravenous Immune Globulin Utilization Management Guidelines. The Blood Programs Coordinating Office at the Ministry of Health and Long-term Care acknowledged that work and more recently has launched an IVIG strategy. Part of the strategy was to formally endorse the Ontario IVIG Utilization Management Guidelines.

Version 2.0 of the guidelines accompany this document. A document titled “Ontario Intravenous Immune Globulin Strategy” is also included to describe the overall strategy and the place the guidelines hold within that strategy. This summary of guidelines and information on IVIG utilization has been prepared specifically for use in Ontario. The Ontario IVIG Advisory Panel that prepared this document reviewed existing, recently published Canadian guidelines for IVIG utilization. For a few medical conditions in specialties for which Canadian guidelines were not available, recently published Australian and United Kingdom IVIG utilization guidelines were considered. The guidelines document provides clinicians information about the common and clinically appropriate uses of Intravenous Immune Globulin, using literature as of March 31, 2012. It is critically important that physicians in each hospital are aware of this information.

Recommendations on Maximum Dose of IVIG

Recommendations on Maximum Dose of IVIG
For the following clinical indications that appear on the Ontario IVIG Utilization Management Guidelines under IVIG is recommended, the maximum dose is 2 g/kg per treatment course, as quoted in the Feasby et al article listed below:

- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Dermatomyositis

For the following clinical indications that appear on the Ontario IVIG Utilization Management Guidelines under “IVIG is recommended as an Option for treatment,” the maximum dose is 2 g/kg per treatment course, as quoted in the Feasby et al article listed below:

- Lambert-Eaton Myasthenic Syndrome
- Polymyositis
- Stiff Person Syndrome

Source of Maximum Dose Recommendations:

Communication of the guidelines documents:

1. Electronic copies can be downloaded from www.transfusionontario.org
   - Ontario Regional Blood Coordinating Network Southwestern Ontario office phone number 905 521 2100 x 76850.
2. Poster version is available upon request.
3. Pocket guide version has been replaced by an application available for Blackberry and I-system formats.

Disclaimer
The Ontario IVIG Utilization Management Guidelines are not intended to replace sound clinical judgment concerning a patient’s unique situation. Furthermore, although the advice and information included in these guidelines is believed to be true and accurate at the time of publication, neither the authors nor the publishers can accept any legal responsibility for any errors or omissions that were made.
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The Ontario IVIG Utilization Management Guidelines are not intended to replace sound clinical judgment concerning a patient’s unique situation.

Furthermore, although the advice and information contained in these guidelines is believed to be true and accurate at the time of going to press, neither the authors nor the publishers can accept any legal responsibility for any errors or omissions that may have been made.
Introduction

The information in this document is version 2.0 of the Ontario Intravenous Immune Globulin Management Guidelines. Version 1.0 was first circulated November 5, 2009. The guidelines were also included in the Intravenous Immune Globulin Toolkit, published by the Ontario Regional Blood Coordinating Network in September 2010.

The information in this document is intended as a guideline document for clinicians seeking clarification on the common and clinically appropriate uses of Intravenous Immune Globulin.

This summary of guidelines and information on IVIG Utilization has been prepared specifically for use in Ontario, based on the input from the Ontario IVIG Advisory Panel. This document refers to 2007 Canadian guidelines for IVIG utilization in Hematology and Neurology medical conditions. For Immunology and Solid Organ Transplantation medical conditions, 2010 Canadian guidelines for IVIG utilization were used. For Dermatology, Rheumatology, and Infectious Diseases medical conditions, guidelines from British Columbia, Australia, and the United Kingdom IVIG utilization guidelines were considered.

References

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Medical Condition</th>
<th>Recommendations</th>
<th>Dose/Frequency of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology</td>
<td>Fetal/ Neonatal alloimmune thrombocytopenia (F/NAIT)¹,³,⁴</td>
<td>Pregnant Women with F/NAIT Before Delivery: IVIG is recommended as first line treatment for women with a previously affected pregnancy. Newborn with F/NAIT: IVIG is recommended as adjunct to provision of platelets. Treatment should be under the direction of an obstetrical centre with expertise in F/NAIT.</td>
<td>Maternal dose: weekly 1 g/kg. Infant: an initial dose of 1 g/kg.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Hemolytic Disease of the Fetus and Newborn (HDN)²,³</td>
<td>Infants with HDN and severe hyperbilirubinemia: IVIG is recommended only if total serum bilirubin (TSB) rising despite intensive phototherapy or TSB level within 34-51 micromol/L of the exchange level.</td>
<td>0.5 g/kg over 2 hours. If necessary dose can be repeated in 12 hours.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Idiopathic Thrombocytopenic Purpura (ITP) Adult¹,³</td>
<td>No treatment is required if the platelet count &gt;20 x 10⁹/L. Acute ITP with bleeding: IVIG is recommended as part of multimodality therapy for major or life-threatening bleeding complications and/or clinically important mucocutaneous bleeding. Acute ITP with severe thrombocytopenia but no bleeding: IVIG is not recommended as first-line therapy, except for patients with contraindications to steroids. ITP with no or slow response to adequate doses steroids: IVIG may be considered as a possible adjunctive therapy. Chronic ITP post-splenectomy: IVIG may be considered as a possible adjunctive therapy as a steroid-sparing measure.</td>
<td>Acute ITP: 1 g/kg daily for 2 days. Chronic ITP Postsplenectomy: 0.5 g/kg every 4 weeks; gradually decrease to the minimum effective dose at maximum intervals to maintain safe platelet levels. Implement alternate therapies for patients who do not achieve a durable response for a minimum of 2-3 weeks.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Idiopathic Thrombocytopenic Purpura (ITP) Pediatric¹,³</td>
<td>Acute ITP: IVIG may be considered initial therapy if platelet count &lt; 20 x 10⁹/L. IVIG is recommended as part of multimodal therapy (with platelet and bolus intravenous Methylprednisolone) when the patient has life-threatening bleeding. IVIG is not indicated with mild bleeding (e.g. petechiae, bruises or asymptomatic). Chronic ITP: IVIG may be considered.</td>
<td>Acute or chronic ITP: one dose of 0.8 to 1 g/kg, with a second dose within 48 hours if the platelet count has not increased to above 20 x 10⁹/L. Acute ITP with life-threatening bleeding: 1 g/kg daily for 2 days.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Post-transfusion purpura (PTP)¹</td>
<td>IVIG is recommended as standard first-line therapy for PTP.</td>
<td>1 g/kg daily for 2 days.</td>
</tr>
<tr>
<td>Specialty</td>
<td>Medical Condition</td>
<td>Recommendations</td>
<td>Dose/Frequency of Administration</td>
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</tbody>
</table>
| Neurology | Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)\(^2,3\) | **Acute CIDP:** IVIG is recommended for short-term management of new-onset CIDP or CIDP relapses.  
**Chronic CIDP:** IVIG may be considered in combination with other immunosuppressive therapy for the long-term management of CIDP. | Initial treatment: Total dose of 2 g/kg divided over 2 to 5 days.  
Maintenance therapy: a systematic approach should be taken to determine the minimum effective dose, and continued use of IVIG should be based on objective measures of its sustained effectiveness. Maximum dose per treatment course should not exceed 2 g/kg. |
| Neurology | Guillain-Barré Syndrome (GBS) including Miller-Fisher syndrome and other variants\(^2,3\) | IVIG is recommended for symptoms of grade 3 severity (able to walk with aid) or greater; or symptoms less than grade 3 severity that are progressing. Treatment should be given within 2 weeks of symptom onset. | Adult: Total dose of 2 g/kg divided over 2 to 5 days.  
Pediatric: Total dose of 2 g/kg divided over 2 days. |
| Neurology | Multifocal motor neuropathy (MMN)\(^2,3\) | IVIG is recommended as first-line treatment for MMN. | Initial treatment: Total dose of 2 g/kg divided over 2 to 5 days.  
Maintenance therapy: tailor to the lowest dose that maintains clinical efficacy, usually 1 g/kg or less per treatment course. |
| Neurology | Myasthenia gravis (MG)\(^2,3\) | IVIG recommended for severe exacerbations of myasthenia gravis or myasthenic crises. IVIG is not recommended for patients with chronic MG. | Total dose of 2 g/kg divided over 2 to 5 days. If additional therapy is required, the dose should be adjusted depending upon response and titrated to the minimum effective dose. |
| Dermatology | Dermatomyositis\(^2,3,8\) | Adults: IVIG benefit is established. Option in combination with other agents for patients who have not responded to other immunosuppressive therapies.  
See also Rheumatology for Juvenile Dermatomyositis. | Adult: Total dose of 2 g/kg divided over 2 to 5 days.  
Pediatric: Total dose of 2 g/kg divided over 2 days. Maximum dose should not exceed 2 g/kg. |
| Dermatology | Pemphigus Vulgaris (PV) and Variants\(^3,4\) | Consider IVIG when there is no response or contraindication to corticosteroids and immunosuppressive agents. | Total dose 2 g/kg divided over 2 to 5 days. |
| Rheumatology | Juvenile Dermatomyositis\(^2,3\) | IVIG is recommended when there is a lack of response or contraindication to corticosteroids, Methotrexate and/or Azathioprine therapy. | Initial treatment: Total dose of 2 g/kg divided over 2 days.  
Maintenance therapy: A systematic approach should be taken to determine minimum effective dose. Continued use should be based on objective measures of sustained effectiveness. Maximum dose should not exceed 2 g/kg. |
| Rheumatology | Kawasaki disease\(^3\) | IVIG is recommended when Kawasaki diagnosis confirmed. | 2 g/kg for 1 day (second dose can be given for patients who fail to respond the first time). |
### Infectious Diseases

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Recommendations</th>
<th>Dose/Frequency of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcal toxic shock</td>
<td>IVIG is recommended when evidence of systemic inflammation and end organ hypoperfusion with fever, tachycardia, tachypnea and hypotension.</td>
<td>1 g/kg on day one and 0.5 g/kg per day on days 2 and 3 OR 0.15 g/kg per day for 5 days.</td>
</tr>
<tr>
<td>Invasive Group A streptococcal fasciitis with associated toxic shock</td>
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</tbody>
</table>

### Immunology

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Recommendations</th>
<th>Dose/Frequency of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Immune Deficiency (PID)</td>
<td>IVIG is recommended in hypogammaglobulinemia (total IgG or IgG subclasses reduced) with recurrent bacterial infections.</td>
<td>Adult: 0.4-0.6 g/kg/every 4 weeks OR SCIG 0.1 to 0.5 g/kg/week. Pediatric: 0.3-0.6 g/kg every 4 weeks. Monitor IgG trough level to maintain low range.</td>
</tr>
<tr>
<td>Secondary Immune Deficiency (SID)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematopoietic Stem Cell Transplant in primary immunodeficiencies</td>
<td>IVIG is recommended in PID patients undergoing stem cell transplant.</td>
<td>0.4 to 0.6 g/kg/every 4 weeks; requirements may increase and should be based on clinical outcome.</td>
</tr>
</tbody>
</table>

### Solid Organ Transplantation

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Recommendations</th>
<th>Dose/Frequency of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute antibody mediated rejection in patients who have received living donor/deceased kidney donor transplant</td>
<td>IVIG is recommended.</td>
<td>0.1 g/kg/treatment day, or as a set dose of 2 g/kg total.</td>
</tr>
<tr>
<td>Kidney transplant from living donor to whom the patient is sensitized</td>
<td>IVIG is recommended to decrease donor-specific sensitization.</td>
<td>2 g/kg/month for 4 months.</td>
</tr>
</tbody>
</table>
For the following conditions, IVIG treatment is not recommended for routine use.

When screening requests for approval the following information may be taken into account as there is some evidence for IVIG to be considered as an option.

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Medical Condition</th>
<th>Recommendations/Options</th>
<th>Dose/Frequency of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology</td>
<td>Acquired hemophilia(^1)</td>
<td>IVIG may be considered one option among adjunctive therapies, such as steroids, in urgent situations in this disorder. Life threatening or limb threatening situations only. Not recommended for routine use.</td>
<td>No recommended dose or duration listed.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Acquired red cell aplasia(^1,4)</td>
<td>IVIG is an option for patients with immunologic pure red cell aplasia (PRCA) who have failed other therapies (e.g., prednisone or cyclosporin). IVIG should be considered first-line therapy for viral PRCA associated with parvovirus B19 in immunocompromised patients.</td>
<td>0.5 g/kg weekly for 4 weeks.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Acquired von Willebrand’s disease(^1,4) (AvWD)</td>
<td>IVIG may be considered one option among adjunctive therapies in the treatment of AvWD in urgent situations (e.g., active bleeding or preoperatively). Not recommended for routine use.</td>
<td>No recommended dose or duration listed.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Allogeneic bone marrow or stem cell transplantation(^4)</td>
<td>1) CMV-induced pneumonitis following transplantation: Use IVIg in conjunction with ganciclovir 2) High risk allogeneic stem cell transplantation, prevention of GVHD</td>
<td>1) No recommended dose or duration listed. 2) 0.4 g/kg weekly, starting one day before transplantation and continuing to day 100 post-transplant.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Autoimmune hemolytic anemia(^1,4) (AIHA)</td>
<td>May be considered one option among adjunctive therapies in urgent situations. Not recommended as routine.</td>
<td>No recommended dose or duration listed.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Autoimmune neutropenia(^1,4)</td>
<td>May be considered one option among adjunctive therapies in urgent situations. Not recommended as routine.</td>
<td>No recommended dose or duration listed.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Hemolytic transfusion reaction(^1) (HTR)</td>
<td>IVIG may be considered as an option among supportive therapies for urgent situations in this disorder.</td>
<td>No recommended dose or duration listed.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Hemolytic transfusion reaction in sickle cell disease(^1) (HTRSCD)</td>
<td>IVIG may be considered among the options for treatment of serious, life-threatening, delayed hemolytic transfusion reactions in SCD patients.</td>
<td>No recommended dose or duration listed.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Hemolytic Uremic Syndrome (HUS) and Thrombotic Thrombocytopenic Purpura(^1) (TTP)</td>
<td>IVIG is one option among adjunctive therapies when first-line therapy has failed. Not recommended as first-line therapy in either the pediatric or adult population.</td>
<td>No recommended dose or duration listed.</td>
</tr>
<tr>
<td>Hematology</td>
<td>Virus associated hemophagocytic syndrome(^1) (VAHS)</td>
<td>IVIG may be considered among options for treatment of severe life-threatening VAHS. Not recommended for routine use.</td>
<td>No recommended dose or duration listed.</td>
</tr>
</tbody>
</table>
| Neurology | Acute disseminated encephalomyelitis<sup>2,4</sup> (ADEM) | IVIG is an option for monophasic ADEM when first-line therapy with high-dose corticosteroids fails or when there are contraindications to steroid use, and for treatment of relapsing ADEM to eliminate steroid dependency or for those patients who fail to respond, or have contraindications, to steroids. | Adults: Total dose of 2 g/kg divided over 2 to 5 days.  
Pediatric: Total dose of 2 g/kg divided over 2 days. |
|---|---|---|---|
| Neurology | Lambert-Eaton Myasthenic Syndrome<sup>2,4</sup> (LEMS) | IVIG is an option for treatment of LEMS. Objective evidence of clinical improvement is needed for sustained use of IVIG. | Initial treatment: Total dose of 2 g/kg divided over 2 to 5 days.  
Maintenance therapy: a systematic approach should be taken to determine the minimum effective dose, and continued use of IVIG should be based on objective measures of its sustained effectiveness. The maximum dose of IVIG per treatment course should be 2 g/kg. |
| Neurology | Multiple sclerosis<sup>2,3</sup> (MS) | IVIG is an option for treatment of patients with relapsing-remitting MS who fail, decline, or are not able to take standard immunomodulatory drug therapies. | 1 g/kg monthly with or without a 5 day induction of 0.4 g/kg daily. |
| Neurology | Pediatric Autoimmune Neuropsychiatric Disorders Associated With Streptococcal Infections<sup>2,4</sup> (PANDAS) | IVIG is an option for treatment of patients with PANDAS. Diagnosis of PANDAS requires expert consultation. | Total dose of 2 g/kg divided over 2 days is recommended as a reasonable option. |
| Neurology | Polymyositis<sup>2</sup> | IVIG may be considered as an option for patients with polymyositis who fail to respond to first-line therapies (e.g., steroids). | Initial treatment: Total dose of 2 g/kg divided over 2 to 5 days.  
Maintenance therapy: A systematic approach should be taken to determine the minimum effective dose, and continued use of IVIG should be based on objective measures of its sustained effectiveness. Maximum dose of IVIG per treatment course should be 2 g/kg. |
| Neurology | Rasmussen's encephalitis<sup>2,4</sup> | IVIG is an option as a short-term, temporizing measure for patients with Rasmussen's encephalitis. Not recommended for long-term therapy. | Adults: Total dose of 2 g/kg divided over 2 to 5 days.  
Pediatric: Total dose of 2 g/kg divided over 2 days. |
| Neurology | Stiff Person's syndrome<sup>2,4</sup> | IVIG is an option for treatment of Stiff Person syndrome if gabaergic medications fail or for patients who have contraindications to gabaergic medications. | Initial treatment:  
Adults: Total dose of 2 g/kg divided over 2 to 5 days.  
Pediatric: Total dose of 2 g/kg divided over 2 days.  
Maintenance therapy: A systematic approach should be taken to determine the minimum effective dose, and continued use of IVIG should be based on objective measures of its sustained effectiveness. Maximum dose of IVIG per treatment course should be 2 g/kg. |
| Dermatology | Toxic epidermal necrolysis/Stevens-Johnson syndrome<sup>4</sup> | IVIG is an option when other treatments are contraindicated, or when the condition is life-threatening. | 1 g/kg daily for 3 days. |
| Solid Organ Transplantation | Kidney transplantation with donor-specific antibodies in recipient<sup>6</sup> | IVIG is recommended. | Insufficient evidence for recommending a dose. |
MOHLTC IVIG Request Form

The form on the following page of this toolkit is intended to be used by hospitals where IVIG is infused.

This form is to be used for all IVIG requests.

Where a request includes multiple infusions of IVIG (e.g. a course of treatment rather than a single infusion), completing the form once is sufficient, until:
- a) Dose is modified, or
- b) Six months have elapsed since the initial treatment was prescribed (all conditions except Primary Immune Deficiency), or
- c) Twelve months have elapsed since the initial treatment for Primary Immune Deficiency.

This type of ordering form can be built into a Laboratory Ordering System or Intranet, or used in paper format. The form is available at www.transfusionontario.org under Toolkits, IVIG. All new requests for IVIG must be ordered using the MOHLTC IVIG Request Form, whether the product is handled through the Transfusion Service or through the Pharmacy. This will ensure that the request is in accordance with provincial guidelines and that any specific prerequisites have been addressed. Hospitals that have already implemented an IVIG Request Form will need to adopt the MOHLTC March 2012 version. Modification of the Request Form is not permitted. This will prevent the addition of indications not on the Guidelines and allow for standardized data collection. A record of completed Request Forms must be kept for five (5) years to allow for spot audits to measure compliance with the IVIG Strategy. The record can be paper based, electronic, or microfilm.
MOHLTC IVIG Request Form

**For Transfusion Medicine or Pharmacy use only**

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Medical Condition</th>
<th>Suggested dose and duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hematology</strong></td>
<td>□ Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)</td>
<td>Maternal dose: weekly 1 g/kg. Infant: an initial dose of 1 g/kg.</td>
</tr>
<tr>
<td></td>
<td>□ Hemolytic Disease of the Fetus and Newborn (HDFN)</td>
<td>0.5 g/kg over 2 hours; if necessary repeat in 12 hours.</td>
</tr>
<tr>
<td></td>
<td>□ Idiopathic Thrombocytopenia Purpura (ITP) Adult</td>
<td>Adult: Acute ITP with bleeding or no response to steroids: 1 g/kg daily for 2 days. Chronic ITP Post splenectomy 0.5 g/kg every 4 weeks. Pediatric: One dose of 0.8 to 1.0 g/kg with a second dose given within 48 hours if the platelet count has not increased to &gt;20x10⁹/L.</td>
</tr>
<tr>
<td></td>
<td>□ Idiopathic Thrombocytopenia Purpura (ITP) Pediatric</td>
<td>Adult: Acute ITP with bleeding or no response to steroids: 1 g/kg daily for 2 days. Chronic ITP Post splenectomy 0.5 g/kg every 4 weeks. Pediatric: One dose of 0.8 to 1.0 g/kg with a second dose given within 48 hours if the platelet count has not increased to &gt;20x10⁹/L.</td>
</tr>
<tr>
<td></td>
<td>□ Post-transfusion Purpura</td>
<td>1 g/kg daily for 2 days.</td>
</tr>
<tr>
<td><strong>Neurology</strong></td>
<td>□ Guillain–Barré Syndrome (GBS) including Miller-Fisher Syndrome and other variants</td>
<td>Adult: Total dose of 2 g/kg divided over 2 to 5 days. Pediatric: Total dose of 2 g/kg divided over 2 days.</td>
</tr>
<tr>
<td></td>
<td>□ Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)</td>
<td>Total dose of 2 g/kg divided over 2 to 5 days.</td>
</tr>
<tr>
<td></td>
<td>□ Multifocal Motor Neuropathy (MMN) initial treatment</td>
<td>Total dose of 2 g/kg divided over 2 to 5 days.</td>
</tr>
<tr>
<td></td>
<td>□ Myasthenia Gravis (MG) initial treatment</td>
<td>Total dose of 2 g/kg divided over 2 to 5 days.</td>
</tr>
<tr>
<td><strong>Dermatology</strong></td>
<td>□ Dermatomyositis</td>
<td>Adult: Total dose of 2 g/kg divided over 2 to 5 days. Pediatric: Total dose of 2 g/kg divided over 2 days.</td>
</tr>
<tr>
<td></td>
<td>□ Pemphigus Vulgaris and variants</td>
<td>Total dose of 2 g/kg divided over 2 to 5 days.</td>
</tr>
<tr>
<td><strong>Rheumatology</strong></td>
<td>□ Juvenile Dermatomyositis (JD) initial treatment</td>
<td>Total dose of 2 g/kg divided over 2 days.</td>
</tr>
<tr>
<td></td>
<td>□ Kawasaki Disease (KD) initial treatment</td>
<td>2 g/kg for 1 day.</td>
</tr>
<tr>
<td><strong>Infectious Diseases</strong></td>
<td>□ Staphylococcal Toxic Shock</td>
<td>1 g/kg on day one and 0.5 g/kg per day on days 2 and 3 OR 0.15 g/kg per day for 5 days.</td>
</tr>
<tr>
<td></td>
<td>□ Invasive Group A streptococcal fasciitis with associated toxic shock</td>
<td>1 g/kg on day one and 0.5 g/kg per day on days 2 and 3 OR 0.15 g/kg per day for 5 days.</td>
</tr>
<tr>
<td><strong>Immunology</strong></td>
<td>□ Primary Immune Deficiency (PID)</td>
<td>Adult: 0.4-0.6 g/kg every 4 weeks or SCIG 0.1-0.5 g/kg/week Pediatric: 0.3-0.6 g/kg every 4 weeks.</td>
</tr>
<tr>
<td></td>
<td>□ Secondary Immune Deficiency (SID)</td>
<td>Primary Diagnosis:</td>
</tr>
<tr>
<td></td>
<td>□ Hematopoietic Stem Cell Transplant in primary immunodeficiencies</td>
<td>0.4-0.6 g/kg every 4 weeks; requirements may increase and should be based on clinical outcome.</td>
</tr>
<tr>
<td><strong>Solid Organ Transplant</strong></td>
<td>□ Acute antibody mediated rejection</td>
<td>0.1 g/kg/treatment day, or as a set dose of 2 g/kg total.</td>
</tr>
<tr>
<td></td>
<td>□ Kidney transplant from living donor (recipient sensitization)</td>
<td>2 g/kg/month for 4 months.</td>
</tr>
</tbody>
</table>

**Other**

Requires Approval: Clinical diagnosis and/or indication for IVIG request:

**For Transfusion Medicine or Pharmacy use only**

- □ Approved
- □ Denied

| Signature of Approving Physician: | Date: |
| □ Dose verified | □ Dose adjusted to: By: |
| □ Confirmed with ordering physician | Date: |

Please fax/send to Transfusion Medicine or Pharmacy

Version 2.0 March 31, 2012
Use of the MOHLTC Intravenous Immune Globulin Request Form

Conditions

This form is to be used for all IVIG requests.

Where a request includes multiple infusions of IVIG (e.g. a course of treatment rather than a single infusion), completing the form once is sufficient, until:

a) Dose is modified, or
b) Six months have elapsed since the initial treatment was prescribed (all conditions except Primary Immune Deficiency), or
c) Twelve months have elapsed since the initial treatment for Primary Immune Deficiency.

Completing the Form

Treating Physician or Designate

1. Complete the date requested and the date required using format YYYY MM DD.
3. Identify treating physician and their specialty e.g. Hematology, Dermatology etc.
4. Identify the total dose per treatment using the dose calculator.*
5. Record IVIG dose and duration of therapy.
6. Check the “Dose calculator used” box if dose was confirmed using the dose calculator.
7. Check the appropriate box to indicate the clinical indication explaining the request (e.g. check box beside Chronic Inflammatory Demyelinating Polyneuropathy).
8. Check ‘Other’ if the clinical indication does not appear on the list; requests for ‘Other’ indications are subject to screening.
9. Document the platelet count in ITP, IgG level in PID and SID or other relevant test results as required.
10. Evaluate the clinical outcomes of patients to ensure the treatment continues to be effective and appropriate.

Health care professional receiving the request (e.g. laboratory technologist, pharmacy personnel)

1. Verify that the clinical indication coincides with one of the clinical indications listed. If not, proceed to step 4.
2. Verify the dose requested using the dose calculator.
3. Doses that require adjustment must be confirmed with the treating physician and documented on the bottom of the form.
4. Requests listing ‘Other’ as the clinical indication should be referred to an approving physician for screening.

Approving Physician or Designate

1. Screening of all IVIG requests for clinical indications listed under ‘Other’ is required.
2. Document whether the request is approved or denied using the shaded area at the bottom of the request form including a signature, date and checking the appropriate box.

Supplementary Information

IVIG will always be provided in life-threatening situations.

Hemolytic reactions due to anti-A and/or anti-B in IVIG have been noted.

Patients should be monitored for signs of hemolysis.

CBC, Blood Group and Antibody Screen should be ordered prior to initial infusion.

In Group A, B or AB patients, within 1 week of initial infusion the following tests are recommended:

CBC, Direct Antiglobulin Test, total and direct bilirubin, retic, LDH, and haptoglobin.

*Institutions that do not adopt the dose calculator tool are required to enact an alternative strategy for adjusting the dose for overweight and obese patients.
Standard Infusion Guidelines for IVIG

Standard Infusion Guideline Recommendations for Ontario

Purpose of the Infusion Guideline Recommendations

To provide health care practitioners involved in the infusion of IVIG with best practice information.

Information in this document can be incorporated into institution specific policies and procedures.

- This guideline does not apply to Subcutaneous Infusion Immune Globulin product, e.g. Vivaglobin, Hizentra

General Principles for IVIG Infusion

- Refer to any institution specific policies when infusing IVIG.
- Check the package insert for complete information.
- Rounding doses to the nearest vial size (e.g. 2.5 or 5 g) is appropriate to ensure adequate therapy and efficient use of product.
- Avoid mixing brands at a single visit/infusion.
- Utilize aseptic technique when handling IVIG.
- Pooling of product should be performed in laminar flow hoods in Blood Transfusion Laboratory (BTL) or Pharmacy. (Note: this principle applies for institutions that pool product prior to issue from inventory).
- Avoid bubbles in the IVIG product.

The following practices have minimized bubbles forming in the product.

  - Allow the product to come to room temperature (do not heat).
  - Avoid shaking the product when handling.
  - Following package insert information, place the bottle on a flat surface and spike at a 90° angle through the centre circle of the stopper.

Infusion Guidelines for IVIG

Pre-Infusion

- Verify that the clinical indication for receiving IVIG treatment is documented in patient’s record and/or on IVIG order.
- Verify that informed consent has been obtained
- Assess whether any contraindications for a particular IVIG product exists and identify patients at increased risk for adverse events prior to commencing infusion.
- Review history of previous infusion of IVIG or other blood components
- Assess patient’s clinical status on day of infusion.
- Record patient weight, known allergies, and medications. (Measure patient weight at institution specific recommended intervals).
- Ensure dose reflects patient’s current weight. [Consider dose adjustment for obese patients using weight calculator (see page 30 in toolkit for further information) where institutional policies apply.]
- Determine whether any pre-infusion blood work is required for this infusion event.

  - Blood work may be required for certain patients. This may include platelet count for ITP patients, plasma IgG levels for immune deficiency patients, and/or baseline testing for initial infusions. Obtaining baseline liver and renal function tests may be appropriate for some patients. Patients who are receiving high dose IVIG should be monitored for hemolysis.
Standard Infusion Guidelines for IVIG

Infusion
- **Prime** line with 5% dextrose (refer to package insert for other possible compatible solutions). Use standard vented tubing – no filter is required.
- **Obtain** product from Blood Transfusion Laboratory or Pharmacy.
- **Measure and record** baseline vital signs.
- **Set** initial infusion rate (source: package insert or institutional policy where applicable). An infusion pump is recommended if available. Infusion pumps help with setting precise infusion rates and include air alarms providing added safety when infusing from bottles.
  - **Initial rate:** For first time patients in particular a slow infusion rate (e.g. 0.5 mL/kg/hr) is recommended for the first 15-30 minutes (institution specific).
  - **Check vital signs**
  - **Standard rate:** After the initial time interval and rate, set rate as per manufacturer’s insert or institution specific standard rate
  - **Repeat vital signs at required intervals.**
  - **Maximum rate:** In patients that tolerate rapid infusion, infuse up to manufacturer’s insert recommendation or institution specific standard rate (e.g. 4 mL/kg/hr).
  - **Monitor** patient for signs of adverse reactions. If an adverse reaction is suspected STOP infusion and notify patient’s physician. (Refer to Adverse Event chart included in this toolkit).
  - **Measure and record** vital signs throughout infusion. (e.g. with change in infusion rate, every 30-60 minutes or as per institutional policy).

Post Infusion
- **Complete** documentation including brand, dose and lot numbers of product.
- **Report** adverse events to Blood Transfusion Laboratory.
- **Report** and return to BTL any unused or defective vials including any vials associated with adverse events.
- **Educate** patients, by providing them with a fact sheet including post infusion adverse events instructions.
  - Encourage the reporting of adverse reactions, this can be facilitated using the fact sheet.
**Notes**

- **Patients** receiving large dose/long treatment with IVIG may develop hemolysis, which is defined as follows:
  a fall of at least 10 g/L in hemoglobin (Hb)

  AND

  a positive direct antiglobulin test (DAT)

  AND

  at least two of the following:
  - increased reticulocyte count
  - increased lactate dehydrogenase
  - low haptoglobin
  - hyperbilirubinemia
  - hemoglobinemia
  - hemoglobinuria
  - presence of significant spherocytosis

  (Reference: IVIG Hemolysis Pharmacovigilance Group)

- **Record** the brand of IVIG used at each infusion, at issuing location (BTL or Pharmacy) and/or infusion location (patient’s record).

- **Check** vital signs when switching from one lot number of product to another; it is not necessary to slow down the infusion rate when changing lot numbers.

- **Match** patient’s need to appropriate product.
  - Note: While this was crucial when lyophilized product was in use, it may be less applicable now. (For example, product requirement may vary in terms of IgA content and that is a consideration in certain patients.)

- **Maintain** individual chronically infused patients on the same IVIG product whenever possible.
  - Note: Practice varies on this issue depending on institution and availability of product.
Adverse Events Chart for IVIG Infusion

**STOP infusion and notify patient’s physician if:**
- Significant change* in systolic or diastolic blood pressure.
- Temperature 38°C or more and increased by at least 1.0°C from baseline
- Appearance of flushing, rigors (shaking chills), urticaria, itching, wheezing, tightness in chest, abdominal cramps, headache, nausea/vomiting or red urine.

Report all suspected reactions to Blood Transfusion Laboratory

<table>
<thead>
<tr>
<th>Reaction Type</th>
<th>Signs and Symptoms</th>
<th>Severity</th>
<th>Frequency</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor-possible rate related reactions</td>
<td>Chills; headache; nausea</td>
<td>Mild</td>
<td>Common</td>
<td><strong>First infusion: Stop IVIG, Consult Physician and Report to Blood Transfusion Laboratory</strong>&lt;br&gt;If symptoms are minor the infusion may be restarted at a reduced rate. Recurrent reactions may require appropriate premedication and/or a change in IVIG product&lt;br&gt;Subsequent treatments: May not need to stop IVIG and may not need to report reaction to Blood Transfusion Laboratory-Consult institutional policy.</td>
</tr>
<tr>
<td>Other minor or moderate reactions</td>
<td>Anxiety, fever, rigors, rash, itchiness, flushing, chest, back or abdominal pain, nausea, vomiting, tachycardia, hypo or hypertension</td>
<td>Moderate</td>
<td>Occasional</td>
<td><strong>Stop IVIG, Consult Physician.</strong>&lt;br&gt;Contact physician for assessment and symptomatic treatment. If symptoms are minor the infusion may be continued at a reduced rate. Recurrent reactions require appropriate premedication and/or a change in IVIG product. Report to Blood Transfusion Laboratory</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>Facial and/or tongue swelling, chest tightness, airway edema, dyspnea, hypotension, shock, tachycardia, nausea/vomiting, widespread rash (&gt;2/3 body), anxiety, fever</td>
<td>Severe</td>
<td>Rare</td>
<td><strong>Stop IVIG, Consult Physician.</strong>&lt;br&gt;May require epinephrine promptly. Often reaction to IgA in an IgA deficient patient Report to Blood Transfusion Laboratory</td>
</tr>
<tr>
<td>Acute (&lt;24hr) or delayed (&gt;24hr) hemolysis</td>
<td>Fever, back pain, dyspnea. Changes in urine colour (red/brown urine; fall in hemoglobin (at least 10g/L); increase in indirect bilirubin and in LDH.</td>
<td>Mild to severe</td>
<td>Rare</td>
<td><strong>Stop IVIG, Consult Physician.</strong>&lt;br&gt;Contact physician for assessment. Do not restart. Often due to anti-A antibodies in IVIG directed against a patient whose blood group is A or AB. Report to Blood Transfusion Laboratory</td>
</tr>
<tr>
<td>Aseptic Meningitis</td>
<td>Severe and incapacitating headache with nuchal rigidity, drowsiness, fever, lethargy, photophobia, painful eye movements, nausea, vomiting, diarrrhea, pharyngitis, deterioration of mental status</td>
<td>Severe</td>
<td>Rare</td>
<td><strong>Stop IVIG, Consult Physician</strong>&lt;br&gt;Do not restart&lt;br&gt;Usually resolves spontaneously in 1-2 days. Report to Blood Transfusion Laboratory</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>Peripheral edema, periorbital edema, urination changes, increased serum creatinine, hypertension, back pain, flank pain, blood in urine</td>
<td>Severe</td>
<td>Rare</td>
<td><strong>Stop IVIG, Consult Physician</strong>&lt;br&gt;Predisposing factors: age&gt;65, diabetes mellitus, preexisting renal insufficiency Report to Blood Transfusion Laboratory</td>
</tr>
<tr>
<td>Thromboembolic events</td>
<td>Symptoms related to Myocardial infarction, Transient Ischemic Attack, Stroke, Deep vein thrombosis</td>
<td>Severe</td>
<td>Rare</td>
<td><strong>Stop IVIG, Consult Physician</strong>&lt;br&gt;Causative relationship not clearly understood. Possibly related to increases in viscosity Report to Blood Transfusion Laboratory</td>
</tr>
<tr>
<td>Viral (Prion) Transmission (Delayed)</td>
<td>Variable Diagnosed through transmissible disease tests</td>
<td>Severe</td>
<td>No reported cases of HIV or HBV. No reported HCV since 1995</td>
<td>Effective viral reduction measures. Prion (vCJD) transmission theoretical risk Report to Blood Transfusion Laboratory</td>
</tr>
</tbody>
</table>

* Significant change is 20 percent or more.
What is IVIG?
Intravenous Immune Globulin (IVIG) is a blood product that contains antibodies in a concentrated form. It is made from plasma collected from human blood donors. There are several different brands of IVIG in Canada and they are all similar in effect.

Risks
IVIG is considered to be a safe blood product with a low risk of transmitting disease. Blood donors are carefully tested before they donate, and during manufacturing IVIG is treated to destroy the viruses that cause HIV, Hepatitis B and Hepatitis C.

Why am I getting it? What does it do?
IVIG is used to replace antibodies in patients that have lower than normal levels (e.g. Primary Immunodeficiency). These antibodies help to fight infections. It can also be used to treat other conditions, some in which the body attacks its own tissues or organs (e.g. autoimmune disease). Ask your doctor to explain your individual treatment with IVIG.

How is it given?
Your doctor will ask you to give your consent for blood transfusion. Your nurse will start an intravenous (IV) line. IVIG is given through a vein in your arm or hand. It is a clear liquid that comes in glass bottles or plastic bags and is given slowly over several hours. Your nurse will check your vital signs (blood pressure, temperature and pulse) before and during the infusion.

Side effects
Side effects from IVIG usually occur during or up to 24 hours following infusion and tend to be mild and short lived. Patients who are well hydrated before infusion seem to have fewer side effects.

5-10% of patients experience minor side effects related to the rate of transfusion, these can often be reduced by slowing the rate of infusion and giving other medications such as Tylenol® or Benadryl®.

Seek immediate, emergency medical attention if you experience:

- Severe headache, eye pain, extreme drowsiness.
- Facial and/or tongue swelling
- Shortness of breath, chest tightness
- Changes in urine colour (red urine, dark coloured urine)
- Intense back pain

It is important to report any of these symptoms to your doctor or nurse. If this happens after you have returned home it is important to notify your caregivers either immediately or at next clinic visit.
Implementing a Dose Calculator

IVIG therapy has been used for many years to treat both primary immune deficiency patients and patients with several autoimmune disorders. While its usefulness in treatment cannot be denied, caregivers need to remember IVIG must be used with caution. One issue of particular concern is the proper dosage of product, especially in the obese patient.

According to Statistics Canada’s published data for 2005, the rate of Canadians in the obese category (body mass index higher than 30kg/m2) has almost doubled between 1978 and 2005, rising from 13.8% to 24.3% of the adult population, almost 1 in 4 individuals. In 2005, the number of obese Canadians 18 or older was 5.5 million; 36% of the adult population was considered overweight.

The dose of IVIG administered varies depending on the clinical indication. In the case of obese patients, the appropriate dosing regimen is unclear. There is some agreement in the literature that IVIG should be dosed using actual body weight in patients weighing up to 100 kg, with a body mass index less than 30 kg/m2. In contrast, obese patients should have IVIG dosing calculated using an adjusted body weight to account for the increase in volume of distribution (Vd) without accounting for the increase in fat.

Adverse reactions due to IVIG are substantially more likely to happen when a high dose of the product is infused. Adverse reactions are summarized in the Adverse Reactions Chart for IVIG Infusion.

There are jurisdictions in Canada, the United States and abroad where the use of a dose calculator is either in place and recommended, or is in the works for future implementation.

See “Ontario IVIG Strategy” for the policy statement on use of a mechanism to adjust doses for obese patients.

A link to a Dose Calculator tool is available on the Transfusion Ontario website www.transfusionontario.org. The dose calculator is also available in Blackberry or I-system application by searching ‘IVIG” or “ORBCoN”.
References for IVIG Dosing Calculator

6. Aston DL, Lefante J, McNae A. The effect of the introduction of the Criteria for the Clinical Use of Intravenous Immunoglobulin (IVlg) in Australia on the supply of IVlg in Western Australia (Poster session 2010 Transfusion Update Conference)
References

Relevant Sources of Information

4. IVIG National Survey, McMaster Transfusion Research Program
   http://www.transfusionmedicine.ca/resources/clinical-guide-transfusion
9. Canadian Blood Services website, Information for Hospitals
   www.blood.ca
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