

<b>Hamilton Regional Laboratory Medicine Program - HRLMP</b> (effective at Hamilton Health Sciences, St. Joseph's Healthcare and Associated Health Care Facilities)		
Initial Issue Date: Revision Date:	<b>Administration Guidelines</b>	Section: <b>Laboratory Medicine</b> Sub-Section: <i>Transfusion Medicine</i>
Title: <b>Respiratory Syncytial Virus (RSV) Intravenous Immune Globulin (Human)</b>		Document Number:
Approved By: <i>Director, Laboratory Medicine Chair, Regional Transfusion Medicine Committee Head, Transfusion Medicine, HRLMP Manager, Transfusion Medicine, HRLMP Technical Specialist, Transfusion Medicine, HRLMP Chief of Nursing Practice, Hamilton Health Sciences Chief of Nursing Practice, St. Joseph's Healthcare</i>		Page 1 of 3

**Purpose:** To Establish the Indications and Administration of RSV Intravenous Immune Globulin (Respigam)

**Scope:** Applies to all patient care areas across HHS and St. Joseph's Healthcare

**Definitions:** Respigam is a human product made from normal plasma collected from healthy donors that contain high concentration of neutralizing and protective antibodies directed against Respiratory Syncytial Virus (RSV).

<b>Other Names:</b> <b>RESPIGAM</b>	<b>Date Approved:</b>	<b>Pages:</b> 1 of 3								
<b>INDICATIONS:</b>										
<ul style="list-style-type: none"> <li>- Prevention of serious lower respiratory tract infection caused by RSV in children under 24 months of age with bronchopulmonary dysplasia (BPD) or a history of premature birth (&lt; 35 weeks gestation)</li> <li>- Demonstrated to be safe and effective in reducing the incidence and duration of RSV hospitalization and severity of RSV illness in these high risk infants</li> </ul>										
<b>DOSAGE:</b>										
<ul style="list-style-type: none"> <li>- Intravenous use only</li> <li>- Maximum recommended total dosage per monthly infusion is 750 mg/kg</li> </ul> <table style="margin-left: 40px;"> <thead> <tr> <th style="text-align: left;"><u>Time After Start of Infusion</u></th> <th style="text-align: left;"><u>Rate of Infusion</u></th> </tr> </thead> <tbody> <tr> <td>0 to 15 minutes</td> <td>1.5 mL/Kg/hr</td> </tr> <tr> <td>15 to 30 minutes</td> <td>3.0 mL/Kg/hr</td> </tr> <tr> <td>30 minutes to end of infusion</td> <td>6.0 mL/Kg/hr</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <li>- Do not exceed this rate of infusion.</li> </ul>			<u>Time After Start of Infusion</u>	<u>Rate of Infusion</u>	0 to 15 minutes	1.5 mL/Kg/hr	15 to 30 minutes	3.0 mL/Kg/hr	30 minutes to end of infusion	6.0 mL/Kg/hr
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**SUPPLIED:**

– **Special Access Product-must obtain Emergency Drug Release - contact Transfusion Medicine**

– Respigam supplied in single use vials containing either a liquid or lyophilized formulation

<u>Total Quantity of Immunoglobulin</u>	<u>Volume</u>	<u>Concentration</u>
2500 mg $\pm$ 500 mg	50 mL	50 mg $\pm$ 10 mg/mL
1000 mg $\pm$ 200 mg	20 mL	50 mg $\pm$ 10 mg/mL

– Store at between 2 to 8°C - do not freeze  
– Do not use after expiration date

**RECONSTITUTION AND STABILITY:**

- Do not shake vial; avoid foaming
- For lyophilized formulation: reconstitute 2500 mg vial with 47 mL of sterile water for injection, 1000 mg vial with 18.8 mL of sterile water for injection
- Rotate the container gently to wet all undissolved powder and wait 30 minutes for the powder to dissolve
- After the single use vial is entered

**ADMINISTRATION:**

- Infusion should begin within 6 hours and be completed within 12 hours
- Filters not necessary, but an in-line filter with a pore size larger than 15 um may be used

METHOD	WHO/ WHERE	DILUTION	HOW TO ADMINISTER	INFUSION PUMP	PRECAUTIONS AND MONITORING
IV PUSH	N/A	N/A	N/A	N/A	N/A
MINIBAG/ BURETROL	RN	- Should not be further diluted but if necessary, should not be diluted more than 1:2 with 2.5%, 10% or 20% dextrose in water with or without sodium chloride	- Administer product using buretrol or evacuated bottle with a vented administration set	Yes	- Observe and monitor for adverse reactions - notify physician
PRIMARY IV BAG	N/A	N/A	N/A	N/A	N/A
IM or SC	N/A	N/A	N/A	N/A	N/A

**COMPATIBILITIES/INCOMPATIBILITIES:**

- Respigam should not be given to patients with a history of a severe prior reaction associated with the administration of Respigam or other human immunoglobulin preparations
- Patients with IgA deficiencies have potential for developing antibodies to IgA and could have anaphylactic or allergic reactions to subsequent administration
- Antibodies present in immune globulin preparations may interfere with the immune response to live virus vaccines, such as mumps, rubella and particularly, measles - if such vaccines are given during or within 10 months after Respigam infusion, reimmunization is recommended.
- It is not known whether Respigam can cause fetal harm when administered to a pregnant woman

**ADVERSE EFFECTS:**

- Infants with underlying pulmonary disease may be sensitive to extra fluid volume
- During administration, a patient's vital signs should be monitored frequently and a patient should be observed for increases in heart rate, respiratory rate, retractions and rales (crackles)
- Rare occurrences of aseptic meningitis syndrome (AMS) have been reported in association of IGIV treatment
- Respigam is made from human plasma and like other plasma products, carries the possibility for transmission of blood borne pathogenic agents

**MANAGEMENT OF ADVERSE EFFECTS:**

- Notify Physician
- Notify Transfusion Medicine
- Epinephrine (and diphenhydramine) should be available for treatment of severe reactions

**NOTES:**

Manufactured by Genesis Bio-Pharmaceutical, Inc  
Distributed by Canadian Blood Services

**Documentation:**

Issue transfuse sheets or requisitions must be included in patient's chart.  
Written consent for transfusion must be obtained prior to administration.

**References:**

Product Monograph - RESPIGAM<sup>R</sup>  
Respiratory Syncytial Virus Immune Globulin  
Intravenous (Human) (RSV- IGIV) Liquid and Lyophilized Formulations Professed Standard Passive  
Immunizing Agent

**Developed By In Consultation With:**

Transfusion Medicine Operations Group

REVIEW DATES:

REVISION DATES: