IREDELL HEALTH SYSTEM

Adult Intravenous Immunoglobulin (IVIG)	
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P&T Committee	Date: 06/2019

Policy:

Intravenous Immunoglobulin (IVIG) is a fractionated blood product which consists of concentrated immunoglobulin from pooled human plasma. It is used in clinical practice for a variety of immune deficiencies, autoimmune disorders, and inflammatory disorders. This policy refers to both inpatient and outpatient orders.

Procedure:

A. IVIG orders for outpatient services must be completed by provider using the attached order form.
B. All IVIG orders will be reviewed by the pharmacist for appropriate indication and dosing.
C. Inpatient use of IVIG will be evaluated and restricted to patients requiring emergent use. Patients not requiring emergent IVIG therapy will be deferred to receive in the outpatient setting.
D. Upon receipt of order, pharmacy will evaluate the patient's height and weight documented in the electronic medical record (EMR). The RN or LPN must obtain and record an updated height and weight prior to each administration. IVIG will be dosed based on ideal body weight (IBW) unless the patient's weight is greater than or equal to 30% more than IBW, in which case adjusted body weight (AdjBW) will be utilized for dose calculation. Actual body weight (ABW) will be used if the IBW is greater than the ABW. Pharmacists may automatically adjust doses based on these parameters.
    a. Calculations to be used:
        i. IBW in kg (females) = 45.5 + 2.3 x [height (inches) - 60 inches]
        ii. IBW in kg (males) = 50 + 2.3 x [height (inches) - 60 inches]
        iii. AdjBW = IBW + 0.4 (ABW – IBW)
    b. The pharmacist will round the dose to the nearest 5 gm vial. Dose rounding resulting in a more than 10% change in dose will require pharmacist to contact provider prior to change.
    c. ABW may be used if patient is not responding to therapy using IBW/AdjBW.
E. Providers may order IVIG as "flat doses" (ie. X grams). Weight-based dosing is encouraged, as described above. Pharmacy will evaluate "flat doses" to ensure doses do not exceed the recommended dosing regimen.
F. IVIG is restricted to FDA-approved indications and selected non-FDA approved indications. See **Table 1** with corresponding recommended doses.
    a. Doses should be ordered as mg/kg to allow for evaluation of appropriate dose and corresponding ordered indication.
    b. A discussion will be held between the provider and the pharmacist upon order verification if the IVIG indication is not listed in this policy.
    c. Orders received for dosages exceeding the maximum recommended dosing regimen will require pharmacist to contact provider and to document discussion had with provider in the EMR.
G. Orders will be limited to IVIG products on formulary.

Table 1: Indications for IVIG use

FDA-approved indications	Recommended Dosing Regimen
B-cell chronic lymphocytic leukemia (CLL) • Hypogammaglobulinemia AND/OR recurrent infections	400 mg/kg every 3 – 4 weeks
Chronic inflammatory demyelinating polyneuropathy (CIDP)	Loading dose: 2,000 mg/kg in divided doses over 2 – 4 consecutive days Maintenance: 1,000 mg/kg every 3 weeks Alternative: 500mg/kg/day x 2 consecutive days
Immune Thrombocytopenia (ITP) • Must be ordered by hematologist	Initial: 1,000 mg/kg daily for 2 consecutive days OR 400 mg/kg/day x 5 consecutive days
Multifocal motor neuropathy (MNN)	500 – 2,400 mg/kg every 4 weeks based on clinical response
Primary humoral immunodeficiency disorder (PI) • Congenital agammaglobulinemia • Common variable immunodeficiency • Severe combined immunodeficiency • Wiskott-Aldrich Syndrome • X-linked agammaglobulinemia	300 – 600 mg/kg every 3 – 4 weeks (Dose adjusted based on monitored trough serum IgG concentrations and clinical response)
Off-label indications – appropriate based on current clinical evidence	**Recommended Dosing Regimen**
Dermatomyositis • Severe active illness for which other interventions have been unsuccessful or intolerable	2,000 mg/kg per treatment course in divided doses over 2 – 5 consecutive days every 4 weeks Maximum: 2,000 mg/kg per treatment course
Guillain-Barré syndrome	2,000 mg/kg per treatment course in divided doses over 2 – 5 consecutive days
Multiple Sclerosis (MS) – relapsing remitting and have failed other treatments	1,000 mg/kg per month
Myasthenia gravis (MG) • Acute severe decomposition refractory to other therapies	2,000 mg/kg per treatment course in divided doses over 2 – 5 consecutive days

Administration:

1. IVIG, when ordered by the provider, may be given by a RN or LPN. Vital signs may be obtained from a CNA.
2. Vital signs are to be obtained prior to administration, 15 minutes after start of infusion and every 30 minutes thereafter.
3. IVIG should be infused through a separate intravenous line, at room temperature.
4. Established IV line may be flushed with D5W (100-250ml) with unvented primary tubing.
5. IVIG does not need reconstitution. Do not add any medication to the IVIG infusion container. Refer to package insert for instructions for specific product preparation.
6. Prior to the administration of IVIG, explain to the patient the importance of reporting the listed symptoms below. Mild erythema may follow infiltration at the infusion site.
    - Flushing
    - Chest tightness
    - Nausea/vomiting
    - Malaise
    - Back or hip pain
    - Hot skin/fever
    - Dizziness
    - Shortness of breath
    - Excessive coughing
    - Hypotension/hypertension
    - Chills
    - Headache
    - Rash
7. Administer IVIG in the sequence titration listed in **Table 2**. Monitor for infusion reactions. If an infusion reaction occurs, stop the infusion and contact the provider immediately.

Table 2: Rate of Administration of IVIG 10%

Rate of Administration	mg/kg/min	ml/kg/min	ml/kg/hour
first 15 minutes	1	0.01	0.6
next 30 minutes	2	0.02	1.2
next 30 minutes	3	0.03	1.8
next 30 minutes	4	0.04	2.4
next 30 minutes	5	0.05	3
next 30 minutes	6	0.06	3.6
next 30 minutes	7	0.07	4.2
next 30 minutes (maximum rate)	8	0.08	4.8

8. Documentation will be charted according to electronic Medication Administration Record or Blood Transfusion Assessment Sheet.

INITIAL EFFECTIVE DATE:
DATES REVISIONS EFFECTIVE: 02/2019, 04/2019, 06/2019, 08/2022
DATES REVIEWED (no changes): 06/2017

Adult Intravenous Immunoglobulin (IVIG) Order Form

Laboratory
[ ] Serum immunoglobulin level IgG, IgM, and IgA prior to infusion and every _____weeks thereafter.
[ ] Serum Creatinine
[ ] Other: _____

Pre-Medications – Give first dose 30 minutes prior to each administration of IVIG
[ ] acetaminophen 650mg PO x 1 dose
[ ] diphenhydramine 25mg IV x 1 dose
[ ] diphenhydramine 25mg PO x 1 dose
[ ] ondansetron 4mg IV x 1 dose
[ ] famotidine 20mg IV x 1 dose
[ ] Other: _____
[ ] Other: _____
[ ] Other: _____

IVIG Orders – Indication/Recommended Dosing (Provider to order specific dose below)
[ ] B-cell chronic lymphocytic leukemia (CLL)
(*Recommended Dosing Regimen: 400 mg/kg every 3 – 4 weeks*)
[ ] Chronic inflammatory demyelinating polyneuropathy (CIDP)
(*Recommended Dosing Regimen: Loading dose: 2,000 mg/kg in divided doses over 2 – 4 consecutive days, Maintenance: 1,000 mg/kg every 3 weeks, Alternative: 500mg/kg/day x 2 consecutive days*)
[ ] Immune Thrombocytopenia (ITP)
(*Recommended Dosing Regimen: Initial: 1,000 mg/kg daily for 2 consecutive days OR 400 mg/kg/day x 5 consecutive days*)
[ ] Multifocal motor neuropathy (MNN)
(*Recommended Dosing Regimen: 500 – 2,400 mg/kg every 4 weeks based on clinical response*)
[ ] Primary humoral immunodeficiency disorder (PI)
(*Recommended Dosing Regimen: 300 – 600 mg/kg every 3 – 4 weeks*)
[ ] Dermatomyositis
(*Recommended Dosing Regimen: 2,000 mg/kg per treatment course in divided doses over 2 – 5 consecutive days every 4 weeks*)
[ ] Guillain-Barré syndrome
(*Recommended Dosing Regimen: 2,000 mg/kg per treatment course in divided doses over 2 – 5 consecutive days)*
[ ] Multiple Sclerosis (MS)
(*Recommended Dosing Regimen: 1,000 mg/kg per month*)
[ ] Myasthenia gravis (MG)
(*Recommended Dosing Regimen: 2,000 mg/kg per treatment course in divided doses over 2 – 5 consecutive days*)
[ ] OTHER _____

Per P & T Committee, use for indications other than those listed above requires discussion with pharmacist before IVIG may be dispensed and administered.

DOSE: _____mg/kg IV daily for _____ consecutive days every _____ weeks
OR _____ mg/kg IV once every _____ weeks
OR _____ grams IV once every _____ weeks

□ **Use Formulary product**
□ **Use Gamunex – C**

_____ _____ _____
Signature of Provider **Date** **Time**

Version 06-2019

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Citations:

Patient Information Sticker

1. Adbersib, CR, Olson, JA. Correlation of weight-based IV Immunoglobulin doses with changes in serum immunoglobulin G levels. Am J Health-Syst Pharm. 2015; 15:285-289.
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3. Chow S, Salmasi G, Callum JL, Lin Y. Trimming the fat with an IVIG approval process. Transfus Apher Sci. 2012 Jun;46(3):349-52. doi: 10.1016/j.transci.2012.03.030. Epub 2012 Apr 12. PubMed PMID: 22503308.
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6. Rocchio MA, Schurr JW, Hussey AP, Szumita PM. Intravenous Immune Globulin Stewardship Program at a Tertiary Academic Medical Center. Ann Pharmacother. 2017 Feb;51(2):135-139. doi: 10.1177/1060028016673071. Epub 2016 Oct 6. PubMed PMID: 27758967.
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