Everything you ever wanted to know about IVIG, and more!

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What exactly is IVIG?

- Intravenous Immune Globulin
 - Immune Globulin antibody, protein, Y-shaped,
 protect from foreign invaders most common is
 IgG
 - Found in blood plasma
 - Human donors takes thousands to make one dose
 - Plasma is treated to deactivate any potential viral contamination
 - Plasma is purified so that contents are as much IgG as possible and minimize other plasma contents

What exactly is IVIG?

- There is no generic form impossible to replicate an antibody in a lab
- There are several brands which have variances:
 - Manufacturer and their process for viral deactivation and purification, therefore, contents etc.
 - Form powder or liquid
 - Labeled indications
 - Cost

Current Brands of IVIG

Brand	Manufacturer	Concentration	Sugar Content
Carimune® NF	CSL Behring	3% or 6%	Sucrose
Flebogamma®	Grifols	5% and 10%	None
Gammagard Liquid	Baxter	10%	None
Gammagard SD LIGA	Baxter	5%	Glucose
Gammagard SD	Baxter	5%	Glucose
Gammaked™	Kedrion	10%	None
Gammaplex	BPL	5%	Sorbitol
Gamunex®-C	Grifols	10%	None
Octagam®	Octapharma	5%	Maltose
Privigen®	CSL Behring	10%	None

How is it administered?

- Usually through a vein in your arm
- If you have difficulty with IV access, central line in chest is an option – more long term
- Slowly most reactions occur when it is run too quickly
 - Infusion rates are specific to each individual
 - Package insert is the maximum rates for anyone, but side effects tend to decrease the more slowly it is infused

Administration continued

- Start slowly and gradually increase as tolerated
- MD or Pharmacist will determine rates

How is the dose determined?

By weight and diagnosis

EXAMPLE:

Someone with myositis is typically prescribed 2 grams per kilogram.

80 kg person = 160 grams

This would likely be broken up into 4 days of 40 gram each day

Dosing and Administration cont'd

40 grams each day should take about 3-5 hours depending on:

- MD orders
- Any prior treatment with IVIG and how it was tolerated
- How the individual actually tolerates IVIG when administered
- What the package insert for the brand used says
- Any rate restrictions for cardiac or renal issues

Dosing and Administration cont'd

Example – Privigen Prescribing Information

Intravenous Administration Only: ITP and CIDP;

^{*}no brand is labeled for myoitis

Indication*	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	200-800 mg/kg (2- 8 mL/kg) every 3- 4 weeks	0.5 mg/kg/min (0.005 mL/kg/min)	Increase to 8 mg/kg/min (0.08 mL/kg/min)
ITP	1 g/kg (10 mL/kg) for 2 consecutive days	0.5 mg/kg/min (0.005 mL/kg/min)	Increase to 4 mg/kg/min (0.04 mL/kg/min)

What are the side effects of IVIG?

Severe adverse reactions

- Anaphylaxis
- Renal Failure
- Thrombotic Event
- Aseptic Meningitis Syndrome
- Hemolytic Anemia

Infusion-related reactions

- Headache
- Blood pressure changes
- Nausea
- Vomiting
- Dizziness
- Fever
- Fatigue
- Chills

What should be done before the infusion?

- Take any prescribed premedications
- Make sure the IVIG is room temperature before it is infused
- Unless it's contraindicated, hydrate!
- Nurse should take baseline vital signs

What should be done during the infusion?

- Vital signs should be taken prior to any rate changes/increases and at least every 30 minutes
- If you have any side effects tell the nurse

Where is the IVIG administered?

- Hospital outpatient infusion center
- Hospital
- · Physician's office infusion suite
- Home
 - Place of employment



Wherever you receive it, the nurse administering it should have experience and knowledge with IVIGI

Why and when is it used for myositis?

- PM and DM
 - When other therapies are not controlling the condition
 - When other medications are causing intolerable side effects
 - Prednisone
 - immunosuppressants
- IBM
 - To improve swallowing
 - Some small studies done

How does it work?

- Not completely understood, many theories
- Myositis thought to be autoimmune disease
 - Autoimmune disease is where the immune systems perceives part of the body as foreign and attempts to destroy it
 - IVIG suppresses the immune response
 - IVIG has anti-inflammatory properties

How is IVIG covered by my insurance?

- Almost every insurance requires prior authorization for IVIG
- Almost every insurance has a medical policy outlining how IVIG is approved.
- You must prove you have myositis
- You must demonstrate lack of response or toleration of other medications

From TMA's website:

For a diagnosis of dermatomyositis, patients must present with at least one of the skin symptoms listed in "skin lesions" and four of the remaining symptoms.

For a diagnosis of polymyositis, patients present with no skin symptoms and four of the remaining criteria.

- Proximal muscle weakness (upper or lower extremity and trunk)
- Elevated serum CK (creatine kinase) or aldolase level
- Muscle pain on grasping or spontaneous pain
- Myogenic changes on EMG (short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
- Positive anti-Jo-1 (histadyl tRNA synthetase) antibody
- Nondestructive arthritis or arthralgias
- Systemic inflammatory signs (fever: more than 37° C at axilla, elevated serum CRP level or accelerated ESR [erythrocyte sedimentation rate] of more than 20 mm/h by the Westergren method)
- Pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen)

From TMA's website

Skin lesions

- Heliotrope rash (red purple edematous erythema on the upper palpebra)
- Gottron's sign (red purple keratotic, atrophic erythema, or macules on the extensor surface of finger joints)
- Erythema on the extensor surface of extremity joints: slightly raised red purple erythema over elbows or knees

Credits: Modified with permission from Tanimoto K, Nakano K, Kano S, Mori S, Ueki H, Nishitani H, Sato T, Kiuchi T, Ohashi Y. Classification Criteria for Polymyositis and Dermatomyositis. The Journal of Rheumatology. 1995;22:4.

Coverage

- Most insurances have some form of these criteria in their coverage policy (Aetna is exact wording)
- For IBM, it is typically excluded from criteria as not covered
 - Small studies done don't carry a lot of weight with insurances as evidence it is effective
 - Some will allow one or two courses to see if there is benefit

So what do I need to know about IVIG?

- Decide with your physician if it's a therapy for you as well as
 - Where you want to receive it
 - Confirmation that it's covered and how by your insurance
 - The nurse administering it has experience with IVIG administration
 - Know the side effects and how you can minimize and manage them