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What is IG infusion therapy?

- *Intravenous Immune globulin (IVIg) products come from pooled human plasma of approximately a thousand or more blood donors.

- *IVIg are sterile, purified IG products. Each manufacturer has its own process

- *Nanofiltration

- *Solvent/ detergents

IVIg is used to treat various autoimmune and Primary immune diseases

IG can be administered though IV (Intravenous) or SCIg (subcutaneous)

SCIg is self-infused, under the skin



What is IG infusion therapy?

- * SCIG has less side-effects however more frequent dosing.
- * IVIG is not first line of treatment for MG.
- * Used “off label” so its more difficult to get approved through insurance companies.
- * IVIG is used for maintenance treatment or in MG crisis.
- * Multiple IG brand choices. IVIG is available in different concentrations, volumes depending on the manufacturer.
- * Doctors and pharmacists will choose what brand is best for you based on medical history.
- * Stick with the brand you do well on



What is IG infusion therapy?

- SIDE-EFFECTS (most common)
- Headache
- Chills
- Flushing
- HOW TO TREAT SIDE-EFFECTS
- Slowdown infusion rate
- Pre-meds Tylenol, Benadrly
- IV hydration



What is IG infusion therapy?

- SITE OF CARE:
 - Home
 - Infusion suite
 - Hospital
- DOSING
 - Typically given every 3-4 weeks
 - Weight based 1 gram/ kg
 - Initial Loading dose 2 gram/ kg (given over 3-5 days)



What do I need to know about getting a home infusion?

- Hydrate, premeds and slow drip
- Relax and don't get stressed about the infusion. The nice thing about home infusion is that it's in your home and you can kick back and watch television, read a book, take a nap, chat with your nurse, etc. The nurse is there to make sure all goes smoothly and to help you.
- Don't be afraid to speak up if you start feeling bad or start having a headache. That's why the nurse is there. They know what to do and can slow down the drip or give hydration but if you don't speak up, they won't know. You shouldn't go through an infusion feeling bad.



How can a patient be effective in getting the treatment once it's recommended by their doctor? How much influence does a patient have on these decisions?

- Be in constant communication with your doctor, infusion pharmacy as well as your insurance company.
- Make sure you supply your doctor/insurance company with any information they have requested in a timely manner.
- Patients should always be their own best advocate.
- If your physician doesn't want to try a specific treatment, you have the right to seek a second opinion. You are ultimately in charge of your health.



How to get approved for IG Therapy

- Know your insurance guidelines for IG Therapy for MG
 - Most companies require that you are coded as acute exacerbation or refractory MG
 - For refractory MG, you must meet the following requirements: tried and failed 2 or more of standard therapies (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab).
 - Neurologist must be prescribing therapy.
- Who should submit to insurance?
 - Neurologist if you are getting your IVIG in an infusion center
 - Specialty Pharmacy if you are getting your IVIG/SCIG in the home
- All patients will require a prior-authorization
- If you want to be prescribed subcutaneous IG, your specialty pharmacy will need to submit a medical necessity letter with journal articles showing the efficacy of subcutaneous IG for MG



Medicare Coverage

- Part A – Hospital Inpatient
- Part B – Hospital Outpatient Infusion Suites & Physician Infusion Suites
- Part D – Home Infusion
 - Can I afford to get IG Therapy at Home?
 - YES!
 - Shop around for financial assistance, hardship programs at individual specialty pharmacy/home infusion companies
 - Can I choose which company I want to use?
 - Yes
 - Any Willing Provider Laws



Prior Authorization



"Did you get prior authorization before you became ill?"



Prior Authorization

- A prior authorization is an extra step that most insurance companies require before they decide if they are going to pay for expensive specialists, procedures, and specialty therapies (medications).
- During this process, the insurer may request and review medical records, test results, and other information so they can make an informed decisions.
- It will be determined if the service will be deemed medically necessary and identified as a covered service under your insurance policy based on what information was submitted.
- Usually, your doctor or pharmacist is notified in writing or by phone and you will receive a letter.
 - If you are denied you can appeal.
 - **YOU MUST APPEAL!**
 - If you are told you do not need a prior-authorization, make sure or you will be responsible for the bill if you get denied!



IG Assistance Programs

IG Therapy is expensive, and many people have high deductible plans and/or major copays/coinsurance

- Manufacturer Assistance Programs
 - Pfizer has assistance program for brand Panzyga
 - BPL has assistance program for brand Gammalex
- Specialty Pharmacy/Home Infusion Company's own assistance programs
- Infusion Centers have payment plans



COVID-19

- Is IVIG/SCIG safe since it is made from plasma?
 - Yes, the lipid envelope virus is killed during the viral inactivation process when manufacturing Immune Globulin Therapy.
- Is it safe to get my infusions in current site of care?
 - It is important for you to get your therapies, so if you are going to an infusion clinic, make sure that they are still operating. If you are concerned about leaving your house, you could switch to home infusion.
- What are the protocols that are being taken to keep me safe for my home infusion?
 - Patients & Nurses are being screened to make sure they do not have virus.
 - Pharmacies are wearing gowns, masks, and gloves when packing your shipments.
 - Many pharmacies are sending patients hand sanitizer, thermometers, and masks.
 - Nurses are wearing protective gear when infusing.



IG Supply

Many were impacted by the recent IVIG shortage and are concerned that we may go into another shortage.

We need to collect plasma to make IG therapies.

- Blood and Plasma donations are down.
- It takes 6 months from collection of plasma to final product.
- We have product now, but if we don't get collections back up, we can be looking at another shortage.