Immunoglobulin Replacement Therapy: As Individual as You

Thursday, May 19, 2022

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MISSION

Improving the diagnosis, treatment, and quality of life of people affected by primary immunodeficiency through fostering a community empowered by advocacy, education, and research.

VISION

IDF seeks to ensure that everyone in the U.S. affected by PI has a fully informed understanding of

1. the PI diagnosis that affects them,
2. all available treatment options,
3. the expected standard of care,
4. all their opportunities for connection and support within the PI community.

Questions?

https://community.primaryimmune.org/s/newask

800-296-4433

Get Connected Groups

https://primaryimmune.org/support-services

Virtual groups exclusively for individuals & families living with PI

THANK YOU TO OUR SPONSORS

Immunoglobulin (Ig) Replacement Therapy: As Individual as YOU

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Disclosures

CSL Behring: Consultant

Horizon Pharma: Speaker, Advisory board

Grifols: Speaker, Advisory board

Octapharma: Consultant

Takeda: Speaker, Consultant

Koru: Consultant

Immune Deficiency Foundation: Nurse Advisory Committee

Immunoglobulin: What It Is

- A plasma product, manufactured from plasma collected from thousands (usually ~10,000/lot of Ig) of donors
- A solution of antibodies, containing donor antibodies against diseases they have had or against which they have been vaccinated
- Almost all (95-99%) IgG, with very little IgA or IgM
- SAFE! Manufactured using multiple safety steps beginning with donor selection, screening, and specific viral inactivation/removal steps

What It Is Not

- A cure for an antibody deficiency: it will not cause your system to make its own antibodies. It just gives you what you cannot make for yourself or supplements what you already have

So if you don't keep the tank full, you <u>are</u> going to run out of gas

- A cure for [illegible]fection

Goals for Therapy

- To provide protection (prophylaxis) against severe and/or frequent infections

- To provide you with therapy that will help you to live the life YOU want to!

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When you are on Ig therapy, things to remember…

- Know your product and dose!
- Immunoglobulin needs to be on your med list; everyone on your care team needs to know you're on it
- Your prescriber will monitor blood work for Ig levels and potential adverse effects
- Your IgA and IgM are not going to be changed with therapy, immunoglobulin is ~99% IgG
- Routine vaccinations may not be necessary; consult your prescriber
- It may have an impact on other therapies you need or diagnostics that are done

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So you need immunoglobulin replacement…

You have options

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DECISIONS, DECISIONS…

Route?

Can I do it myself? Do I WANT to?

Product?

Is there a cost difference?

Is one way better than another?

Where to do it?

Side effects?

How long does an infusion take? Do I want it to take?

WHAT'S RIGHT FOR ME???

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Options for Therapy

- Product
- Route of Administration and Timing
  - Intravenously (IVIg) every 3-4 weeks
  - Subcutaneously (SCIg) every 1-14 days
  - Facilitated subcutaneously ($SCIg^{FAC}$) every 2-4 weeks
- Site of Care
  - Home
  - Hospital based infusion suite
  - Free standing infusion suite

Product

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Product?

- All products are approved by the FDA
- All plasma for products given in the US have to be made from plasma collected in the US
- All are safe and equally effective
- Differ in concentration, stabilizers and viral inactivation processes

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Route of Administration

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	IVIg	Facilitated SCIg	SCIg
Frequency of dosing	Every three to four weeks	Every two, three or four weeks	From daily to every 14 days
IgG level	Achieves an initial high concentration of IgG which decreases gradually over approximately 21 days	There is an initial peak and decrease, although not as extreme as with IVIg	No variation in IgG level once steady state is achieved; level stays constant …as long as you infuse 
Access	Requires IV access (NOT A PORT!)	Does not require IV access, patients can do their therapy independently once appropriately trained	
Needle sticks	Usually 1 to establish IV access	1-2	1-4 or more, depending on dose and patient preference
Time of Infusion	Usually three to four hours	Usually three to four hours	Variable as patients desire-there is data supporting safe, rapid (sub 30 minute) infusions and patients who manually push their dose as rapidly as tolerated
Ancillary people	Requires health care professional to establish IV access and monitor infusion	Patients can establish their own subcutaneous access once trained, but therapy requires a committed patient or caregiver	
Intrainfusion systemic side effects?	Possible, including chills, rigors, blood pressure changes, nausea/vomiting, aches	Possible, but to a lesser degree than noted with IVIg	Usually no systemic effects
Pre-medication?	Sometimes necessary	Sometimes necessary	NO, as drug is not biologically available for 24-36 hours
Intrainfusion local side effects?	Not usually, unless IV infiltrates	Redness and swelling are expected especially at start of therapy, sometimes some itching and burning occur	
Post infusion side effects?	Systemic side effects possible	Both local and systemic post-infusion side effects are possible	Not usually expected, and do not occur immediately
Portable?	No	No	Yes
Cost	Cost for drug and nursing/infusion center	Cost for drug and supplies	Cost for drug and supplies

Subcutaneous (SCIg) Parameters

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[CON]	FREQ	# SITES	RATE (mL/hr/site)	VOLUME (mL/site)
16.5%	Weekly	6	1-6 ≤20, ↑25	1-6 ≤25, ↑40
20%	Daily-q 14 days	4	#1-2:10-20, ↑≤ 60 #1-2:10-20, ↑≤ 60	# 1-2: ≤20,↑≤ 60 ≤ 60
10%	Weekly	1-8	20-30 15-20	30 20
10%	Weekly	1-8	20 15-20 10	Not specified in product monograph
20%	Daily-q 14 days	8	25	25
10%	q 3-4 weeks	1-2	7 week ramp up 25-50-75-100% of dose	up to 300
20%	2-7 days	6	<25	25

Understanding the differences and options…

whether they are clinically important or
are advantages or disadvantages
should be determined by the

Prescriber

AND

Patient

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If you HATE your infusion regimen

Be your own advocate!

Have a discussion with your prescriber and ask to explore options!

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So your SCIg dose is 6 grams per week

Possibilities:

Concentration=Volume (30 mL, 36mL, 60 mL)

Frequency

- 12 grams every two weeks
- 6 grams per week
- 3 grams twice per week
- 2 grams three times per week
- 1 gram daily (with Sundays off)

Number of Needles

Time of Infusion

Push or Pump

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It’s all about the possibilities, because,
Immunoglobulin is like….

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ICE CREAM!

And REMEMBER…

There is ice cream for all…..

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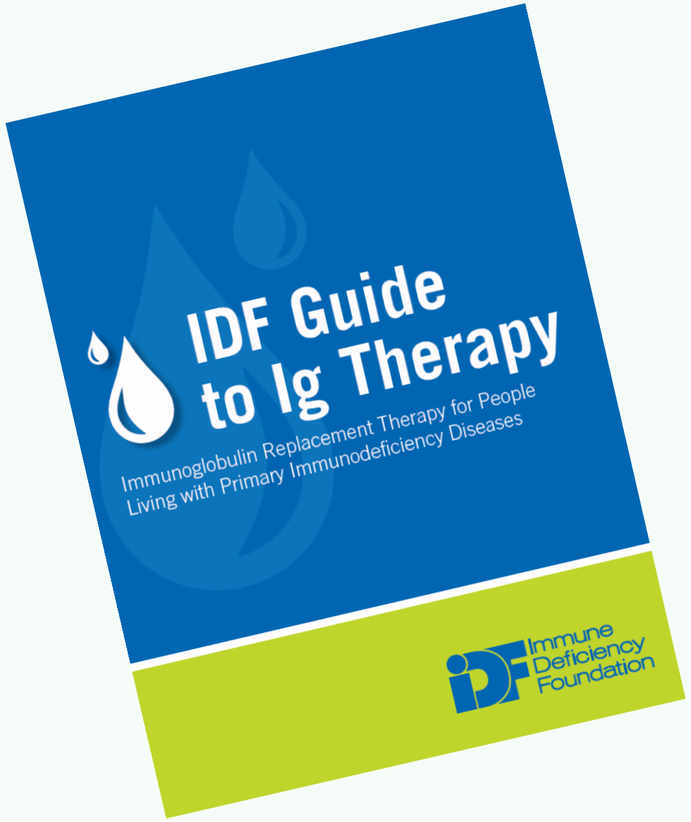
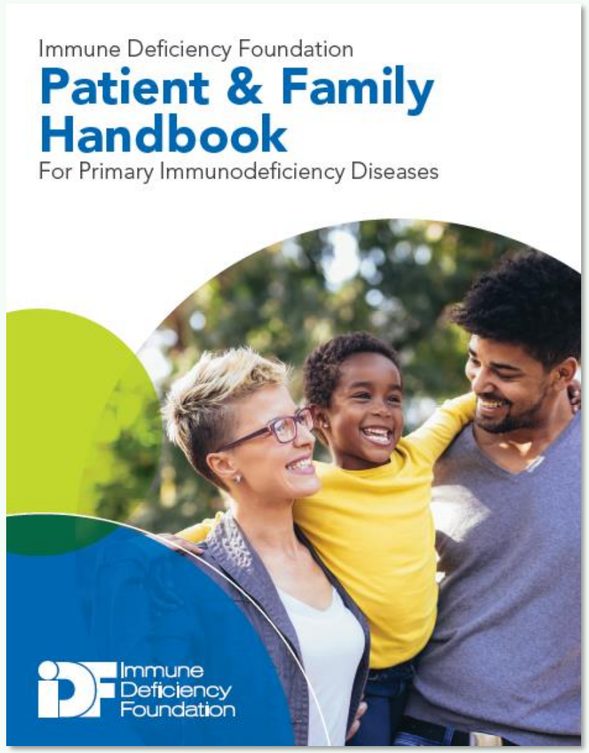
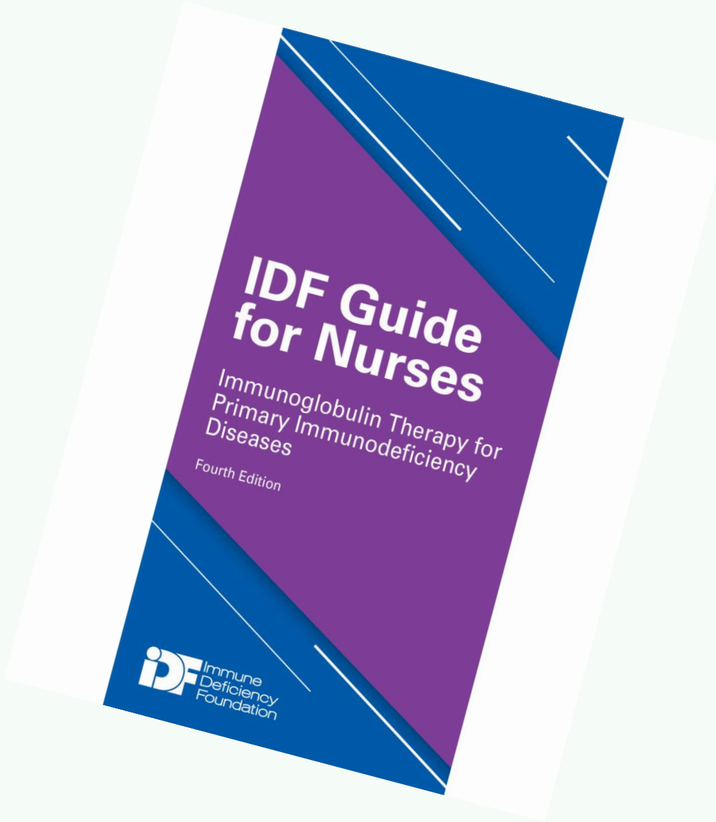
Additional Information About Ig Therapy

https://primaryimmune.org/treatments







https://primaryimmune.org/resource-center

THANK YOU!

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From all of us at IDF

Thank You!

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Lynn Nakeena Elizabeth Cheryl Pat Tawny Aimee
Emma Kathy Alissa Jennifer Brian Doreen Janie
Amy Julieann Adam Wanda STEPHANIE Colleen Becca Maura Kim

You make the IDF community stronger

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