

Immune Globulins:

Therapeutic, Pharmaceutical, Cost, and Administration Considerations

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For the past several years, the availability of immune globulin (Ig) products has been very good, so product shortages have not played a major role in product choice. This allows clinicians to match the best product to the patient based on clinical condition and comorbidities.

New products have become available, providing more treatment options. There now are 5 Ig products indicated for subcutaneous (SQ) use in patients with primary immunodeficiency: Gammagard Liquid (Baxter), Gammaked (Kedrion), Gamunex-C (Grifols) come in 10% concentrations and can be administered intravenously or subcutaneously; Hizentra (CSL Behring) comes in a 20% concentration and can be administered subcutaneously. It should be noted that dosing adjustments are required for all SQ agents when converting from IV.

Hyqvia (Baxter) is the newest SQ Ig product that became available in September 2014. While the IgG portion of the product is identical to Gammagard Liquid 10%, it is to be used in combination with recombinant human hyaluronidase (HY). This combination product allows for SQ administration of a large amount of Ig, equivalent in dose to that of IVIG, in one site and equivalent in conversion ratio on a 1:1 basis. It is FDA-approved for primary immunodeficiency in adults. This is the first product of its type. In the chart it will look identical to Gammagard Liquid 10%, but will be distributed as a dual package with the 5 mL vial of HY. Instructions for administration are unique and specific to this product.

Two products, Gammaked and Gamunex-C, are approved for use in patients with chronic inflammatory demyelinating polyneuropathy (IV only). Gammagard Liquid is approved to treat multifocal motor neuropathy.

A common question regarding Ig products relates to whether they are all the same. Although clinicians have considered all Ig products to have comparable efficacy, they are not pharmaceutically equivalent. It is imperative that Ig products not be interchanged without full



consideration of the pharmaceutical differences.

The reasons for switching products may be clinical in nature and related to tolerability; they may be fiscal and based on contracting issues; or they may be due to product availability. It is best to consider product changes as if the patient is naive to Ig use, with increased monitoring and conservative infusion times.

Whereas Tables 1 to 5 may help facilitate these decisions, it is important to understand the clinical impact of changing products. Although all of the products contain primarily IgG, trace amounts of other Igs—IgA and IgM—as well as widely different stabilizing agents, may affect tolerability. The differences in salt, sugar, and overall osmolality of these products are particularly important when patients have various comorbidities, such as renal dysfunction, diabetes mellitus, vascular disease, or heart failure. Differences between lyophilized and liquid products may result in changes in product concentration and infusion rate, as well as tolerability.

The tables in this review may be helpful for providing optimal care for patients receiving Ig products. They should be used as a general guide to help determine the product that is best suited for a particular patient population. Because there is variation from batch to batch, the exact numbers represent averages of selected batches; any one batch of any Ig product may have ranges outside these average numbers. When comparing administration rates, clinicians need to keep in mind that each patient has a maximum tolerated rate. This rate may be different for each Ig product. Ig must be administered slowly initially and titrated as tolerated. The rate also should be adjusted based on comorbidities. The infusion should be slowed or stopped if adverse events (AEs) become evident during the infusion.

(See the prescribing information for each agent for more information about AEs.)

Table 1. Therapeutic Considerations

Product ^a	Manufacturer	FDA-Approved Indications	IgA Content	pH (after reconstitution)	Plasma Source	Half-life, d ^b	Pathogen Inactivation/Removal
Bivigam 10%	Biotest Pharmaceuticals Medical info: (800) 458-4244 www.biotestpharma.com www.bivigam.com	PID	≤200 mcg/mL	4.0-4.6	Plasmapheresis, US donors from FDA-registered sites	30	Precipitation and removal of fraction III from resuspended fraction II+III, SD, 35 nm filtration
Carimune NF	CSL Behring Customer service: (800) 683-1288 Medical info: (800) 504-5434 www.cslbehring.com	ITP, PID	1,000-2,000 mcg/mL (6%)	6.4-6.8	Plasmapheresis, US donors (>16,000)	23	pH 4.0/pepsin, nanofiltration, TSE removal
Flebogamma 5% DIF Flebogamma 10% DIF	Instituto Grifols SA Barcelona, Spain Grifols Biologicals Inc. Los Angeles, CA 90032 Customer service: (888) GRIFOLS www.grifols.com	PID	<3.2 mcg/mL ^{c,d}	5.6±0.1 (5%) ^{c,d} 5.5±0 (10%) ^{c,d}	US source IQPP-certified plasma from FDA-registered sites	4-week dosing: 32±5 (5%) 37±13 (10%)	Pasteurization (60°C, 10 h), SD, 20 nm nanofiltration, fraction I precipitation, fraction II+III incubation, PEG precipitation, acid treatment, TSE removal
Gammagard Liquid 10%	Baxalta Medical information U.S: (toll free). (866)-424-6724; (244)-948-1849 medinfo.us@baxalta.com	MMN, PID	37 mcg/mL	4.6-5.1	Plasma from FDA-registered sites	35	SD, low pH, nanofiltration
Gammagard S/D 5%	Baxalta Medical information U.S: (toll free). (866)-424-6724; (244)-948-1849 medinfo.us@baxalta.com	CLL, ITP, KD, PID	<1 mcg/mL ^e	6.4-7.2	Plasmapheresis, 10,000 donors from FDA-registered sites	37.7±15	SD
Gammaked 10%	Manufactured by Grifols Therapeutics Inc for Kedrion Biopharma Customer service/medical info: (855) 353-7466; www.gammaked.com; www.kedrion.com	CIDP, ITP, PID ^f	47±13 mcg/mL ^{c,d}	4.0-4.5 ^{c,d}	US source IQPP-certified plasma from FDA-registered sites	35	Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, low pH incubation, TSE removal
Gammaplex 5%	Bio Products Laboratory Ltd Customer service: (800) 843-7477 http://www.gammaplex.com	ITP, PID	<10 mcg/mL	4.8-5.1	U.S. source plasma from FDA-registered sites	4-week dosing: 41±14	SD, nanofiltration, terminal low pH incubation
Gamunex-C 10%	Grifols Therapeutics Inc Research Triangle Park, NC 27709 Customer service: (800) 243-4153 Medical info: (800) 520-2807 www.gamunex-c.com	CIDP, ITP, PID ^f	51±1.4 mcg/mL ^{c,d}	4.0-4.5 ^{c,d}	US source IQPP-certified plasma from FDA-registered sites	35	Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, low pH incubation, TSE removal
Hizentra 20%	CSL Behring Customer service: (800) 683-1288 Medical info: (800) 504-5434 www.cslbehring.com www.hizentra.com	PID SQ only	≤50 mcg/mL	4.6-5.2	Plasmapheresis, US donors	NA	pH 4.0 incubation, nanofiltration, depth filtration, virus filtration, TSE reduction
Hyqvia (IgG 10% + HY 5%)	Baxter Healthcare Corp Direct inquiries: (800) 423-2090 www.baxter.com	PID	37 mcg/mL	4.6-5.1	Plasma from FDA-registered sites	35	SD, low pH, nanofiltration
Octagam 5%	Octapharma USA Customer service: (866) 766-4860 www.octapharma.com	PID	<200 mcg/mL ^g	5.1-6.0	US source and recovered plasma from FDA-registered sites	40	Cold ethanol, pH 4.0 incubation, SD
Octagam 10%	Octapharma USA Customer service: (866) 766-4860 www.octapharma.com	Chronic ITP	106 mcg/mL	4.5-5.0	US source and recovered plasma from FDA-registered sites	36-40	Cold ethanol, pH 4.0 incubation, SD
Privigen 10%	CSL Behring Customer service: (800) 683-1288 Medical info: (800) 504-5434 www.cslbehring.com; www.privigen.com	ITP, PID	≤25 mcg/mL	4.6-5.0	Plasmapheresis, US donors (≥60,000)	36.6	pH 4.0 incubation, 20 nm virus filtration, depth filtration, TSE removal

IgG Subclass, % ^c				Diphtheria Toxin ^c	Streptococcus pneumoniae ^c		Haemophilus influenzae Type B ^c	Streptolysin O ^c	CMV ^c	HAV ^c	HBV (Surface Antibody) ^c	Herpes Simplex Type 1 ^c	Polio Type 2 ^c
IgG1	IgG2	IgG3	IgG4		Type 1	Type 3							
62.5	30.1	6	1.4	18.2 IU/mL	NA	NA	NA	NA	NA	NA	17 IU/mL	NA	Type 1: 0.99 x Ref (176)
60.5	30.2	6.6	2.8	3.6 IU/mL (NT)	313 (EIA)	180 (EIA)	1:60 (CF)	300 IU/mL (HAI)	1:512 (IFA); 1:2,560 (EIA)	1:348 (RIA)	1:64 (RIA)	1:128 (CF)	1:64 (NT)
66.6	28.5 (5%) 27.9 (10%)	2.7 (5%) 3.0 (10%)	2.2 (5%) 2.5 (10%)	7.0±1.0 IU/mL (5%); 13.7±1.4 IU/mL (10%)	NA	NA	15±1 mg/L (5%)	NA	30±6 PEI U/mL (5%); 36±7 IU/mL (10%)	21±4 IU/mL (5%)	88.0±41.8 IU/g Ig (5%); 80.7±23.0 IU/g Ig (10%)	NA	NA
60.9	32.1	5	2.1	4.0 U/mL (NT)	NA	21.2 mcg/mL (EIA)	1:2,320 (EIA)	NA	68 PEI U/mL (EIA)	16.4 IU/mL (RIA)	≥0.20 IU/mL (EIA)	VZV: 32 U/mL (NT)	Type 1: 1:190 mIU/mL (NT)
67	25	5	3	2-5 IU/mL (NT); J5 lipid A 1:273	17.5 mcgAbN/mL (EIA)	8.5 mcg/mL (EIA)	11 mcg/mL (EIA)	1,150 IU (HH)	37 PEI mcg/mL (EIA), 1:2,480 (NT)	1:267 (RIA)	820 mIU/mL (RIA)	1:1,000 (EIA)	1:305 (NT)
62.8	29.7	4.8	2.7	7±2 AU/mL	87.4±22.2 mcg/mL	26.1±7.7 mcg/mL	13.0±2.4 mcg/mL	16,846±13,648 Todd U/mL	57 PEI U/mL	1:139	65±19 IU/g Ig	NA	1:22±0.35
64	30	5	1	2.2 IU/mL	2.3 mcg/mL	NA	791 mcg/mL	185 IU/mL	431 U/mL	20 IU/mL	4.7 IU/mL	5,129 AU/mL	NA
62.8	29.7	4.8	2.7	7±2 AU/mL	87.4±22.2 mcg/mL	26.1±7.7 mcg/mL	13.0±2.4 mcg/mL	16,846±13,648 Todd U/mL	57 PEI U/mL	1:139	65±19 IU/g Ig	NA	1:22±0.35
68.7	26.6	2.7	2	≥2.5 IU/mL	NA	NA	NA	≥1,000 IU/mL	NA	NA	≥0.4 IU/mL	NA	NA
60.9	32.1	5	2.1	4.0 U/mL (NT)	NA	21.2 mcg/mL (EIA)	1:2,320 (EIA)	NA	68 PEI U/mL (EIA)	16.4 IU/mL (RIA)	≥0.20 IU/mL (EIA)	VZV: 32 U/mL (NT)	Type 1: 1:190 mIU/mL (NT)
65	30	3	2	5-30 IU/mL	NA	NA	NA	600-800 IU/mL	33-40 IU/mL	21-25 IU/mL	51 IU/g	1:8,192	1:160-1:320 (NT)
65	30	3	2										
67.8	28.7	2.3	1.2	4.9 (3.8-7.3) IU/mL	NA	NA	36.1 (26.4-45.0) IU/mL	1,746 (1,310-2,010) IU/mL	76.4 (51.2-116.8) IU/mL	NA	5.3 (3.0-10.1) IU/mL	NA	NA

Table 2. Pharmaceutical Considerations

Product ^a	Method of Preparation	Available Dosing Forms	Form	Gamma Globulin, %	Monomers, %
Bivigam 10%	Cohn-Oncley, ^h cold ethanol fractionation, SD	IV	Liquid	≥96	100 monomers + dimers
Carimune NF	Kistler-Nitschmann, ^h pH 4.0 + trace pepsin, nanofiltration	IV	Lyophilized	≥96	92
Flebogamma 5% DIF Flebogamma 10% DIF	Cohn-Oncley, ^h ion-exchange chromatography, acid pH treatment, PEG precipitation, SD, pasteurization, dual nanofiltration (35+20 nm)	IV	Liquid	≥99 ^{c,d}	>99.95 monomers + dimers (5%) ^{c,d} >99.89 monomers + dimers (10%) ^{c,d}
Gammagard Liquid 10%	Cohn-Oncley, ^h anion-exchange chromatography, SD, nanofiltration, ultrafiltration, low pH incubation	IV, SQ (SQ for PID only)	Liquid	≥98	≥95 monomers + dimers
Gammagard S/D 5%	Cohn-Oncley, ^h ultrafiltration, anion-exchange chromatography, SD	IV	Lyophilized	≥90	96.4
Gammaked 10%	Cold ethanol fractionation, anion-exchange chromatography, caprylate chromatography purified, low pH incubation	IV, SQ (SQ for PID only)	Liquid	100	100 monomers + dimers ^{c,d}
Gammaplex 5%	Cold ethanol fractionation, ion-exchange chromatography, SD, nanofiltration (20 nm), ultrafiltration, terminal low pH incubation	IV	Liquid	>99	≥99 monomers + dimers
Gamunex-C 10%	Cold ethanol fractionation, anion-exchange chromatography, caprylate chromatography purified, low pH incubation	IV, SQ (SQ for PID only)	Liquid	100	100 monomers + dimers ^{c,d}
Hizentra 20%	Cold ethanol fractionation, anion-exchange chromatography, octanoic acid fractionation, pH 4.0 incubation, depth filtration, nanofiltration (20 nm)	SQ	Liquid	≥98	≥90 monomers + dimers
Hyqvia (IgG 10% + HY 5%)	Cohn-Oncley, ^h anion-exchange chromatography, SD, nanofiltration, ultrafiltration, low pH incubation	SQ	Liquid	≥98	≥95 monomers + dimers
Octagam 5%	Cold ethanol fractionation, ultrafiltration, chromatography, SD, pH 4.0 incubation	IV	Liquid	≥96	≥90 monomers + dimers
Octagam 10%	Cold ethanol fractionation, ultrafiltration, chromatography, SD, pH 4.0 incubation	IV	Liquid	≥96	≥94 monomers + dimers
Privigen 10%	Cold ethanol fractionation, octanoic acid fractionation, anion-exchange chromatography, pH 4.0 incubation, depth filtration, nanofiltration (20 nm)	IV	Liquid	≥98	≥98 monomers + dimers

Footnotes on page 72; Key on page 74.

IgM Content	Albumin	PEG	Sodium Content	Stabilizer	Osmolality/Osmolarity
2.3 mcg/mL	<0.5%	NA	100-140 mEq/L	Glycine	≤510 mOsm/kg
Trace	0	0	0% water, 0.9% NS	5% sucrose	In sterile water: 3%, 192 mOsm/kg; 6%, 384 mOsm/kg; 12%, 768 mOsm/kg In NS: 3%, 498 mOsm/kg; 6%, 690 mOsm/kg; 12%, 1,074 mOsm/kg
Trace	<2 mcg/mL (5%) ^{c,d} <5 mcg/mL (10%) ^{c,d}	Not detectable	Trace (<3.2 mEq/L) ^{c,d}	5% sorbitol (polyol)	326±5.1 mOsm/kg (5%) ^{c,d} 343±6.1 mOsm/kg (10%) ^{c,d}
Trace	NA	Not detectable	No sodium added	Glycine	240-300 mOsm/kg
Trace	<3 mg/mL	<2 mg/mL	0.85%	2% glucose, glycine	636 mOsm/L (5%), 1,250 mOsm/L (10%) ⁱ
Trace	<2 mcg/mL ^{c,d}	0	Trace (<7 mEq/L) ^{c,d}	Glycine	264±3 mOsm/kg ^{c,d}
<0.02 mcg/mL ^j	0 ^j	0 ^j	30-50 mEq/L	Sorbitol, glycine, and polysorbate 80	420-500 mOsm/kg, but not less than 240 mOsm/kg
Trace	<2 mcg/mL ^{c,d}	0	Trace (<7 mEq/L) ^{c,d}	Glycine	264±3 mOsm/kg ^{c,d}
Trace	≤2 mcg/mL	NA	Trace	Proline	380 mOsm/kg
Trace	NA	Not detectable	No sodium added	Glycine	240-300 mOsm/kg
≤0.1 mg/mL	0	0	≤30 mmol/L	10% Maltose ^k	310-380 mOsm/kg
<106 mcg/mL	0	0	≤30 mmol/L	Maltose (90 mg/mL)	310-380 mOsm/kg
3 mg/L	Trace	0	Trace	Proline	240-440 mOsm/kg

Table 3. Cost Consideration Criteria

Product ^a	Supply	Storage ^l	Distribution	Return Policy Warranty	Packaging or Labeling Enhancements
Bivigam 10%	5, 10 g	2°C-8°C, 24 mo; do not freeze	Wholesaler or direct	Shipping error; defective or damaged product; no out-of-date products	Tamper-evident seal, peel-off label with name, latex-free packaging, lot number, expiration date
Carimune NF	3, 6, 12 g	≤30°C, 24 mo	Wholesaler or direct	Shipping error; defective or damaged product; no out-of-date products	Tamper-evident seal, RSS barcode, peel-off label with lot number, expiration date
Flebogamma 5% DIF Flebogamma 10% DIF	2.5, 5, 10, 20 g (5%); 5, 10, 20 g (10%)	2°C-25°C, 24 mo; do not freeze	Wholesaler or direct	Shipping error; defective or damaged product; no out-of-date products	Tamper-evident seal with hologram, prior handling recognition, integral suspension band, laser-etched vials with UIN, barcode, peel-off label with product lot number
Gammagard Liquid 10%	1, 2.5, 5, 10, 20, 30 g	2°C-8°C, 36 mo; ≤25°C, 24 mo; do not freeze	Wholesaler or direct	No	Latex-free packaging, tamper-evident cap, RSS barcode, peel-off label with lot number, expiration date
Gammagard S/D 5%	2.5, 5, 10 g	≤25°C, 24 mo; do not freeze	Wholesaler or direct	No	Tamper-evident cap, peel-off label with lot number, expiration date
Gammaked 10%	1, 2.5, 5, 10, 20 g	2°C-8°C, 36 mo; ≤25°C, 6 mo; do not freeze	Wholesaler	Shipping error; defective or damaged product; no out-of-date products	Tamper-evident cap, laser-etched vials with UIN, NDC barcode, integral suspension band on larger vial sizes, peel-off label with product lot number, vial stopper not made with natural rubber latex
Gammalex 5%	5, 10, 20 g	2°C-25°C, 24 mo; do not freeze	Wholesaler	Shipping error; defective or damaged product; no out-of-date products	Latex-free, single-use vial, tamper-evident cap, peel-off label with lot number, expiration date
Gamunex-C 10%	1, 2.5, 5, 10, 20, 40 g	2°C-8°C, 36 mo; ≤25°C, 6 mo; do not freeze	Wholesaler or direct	Shipping error; defective or damaged product; no out-of-date products	Tamper-evident cap, laser-etched vials with UIN, NDC barcode, integral suspension band on larger vial sizes, peel-off label with product lot number, vial stopper not made with natural rubber latex
Hizentra 20%	1, 2, 4, 10 g	≤25°C, 30 mo	Wholesaler or direct	Shipping error; defective or damaged product; no out-of-date products	Latex-free packaging, single-use tamper-evident vials, peel-off label with lot number, expiration date
Hyqvia (IgG 10% + HY 5%)	2.5, 5, 10, 20, 30 g	2°C-8°C, 36 mo; do not freeze ^m	Wholesaler or direct	No	Latex-free packaging, tamper-evident cap, RSS bar code, peel-off label with lot number, expiration date
Octagam 5%	1, 2.5, 5, 10, 25 g	2°C-25°C, 24 mo; do not freeze	Wholesaler or direct	Shipping error; defective or damaged product; no out-of-date products	Tamper-evident, latex-free packaging, peel-off label with lot number, expiration date
Octagam 10%	2, 5, 10, 20 g	2°C-8°C, 24 mo; ≤25°C, 6 mo; do not freeze	Wholesaler or direct	Shipping error; defective or damaged product; no out-of-date products	Tamper-evident, latex-free packaging, peel-off label with lot number, expiration date
Privigen 10%	5, 10, 20, 40 g	≤25°C, 36 mo	Wholesaler or direct	Shipping error; defective or damaged product; no out-of-date products	Latex-free, single-use vial, tamper-evident seal, RSS barcode, peel-off label with lot number, expiration date

Key on page 74.

FOOTNOTES

- a All agents are contraindicated for IgA deficiency with antibodies to IgA.
- b Varies with disease state, immune status, and age of the patient.
- c Average of sample lots.
- d Data on file at Grifols.
- e As of Dec. 2012, Baxter has discontinued Gammagard S/D 5%; the low IgA product will remain available for patients with known reactions to IgA or IgA deficiency with antibodies; all Gammagard S/D will be manufactured with IgA <1; special request only.
- f DO NOT USE Gammaked or Gamunex-C subcutaneously for ITP or CIDP.
- g With additional purification steps added in 2010, current release lots contain <100 mcg/mL. Data on file at Octapharma.
- h Cohn-Oncley is the original method of cold ethanol

- fractionation; Kistler-Nitschmann is the specific cold ethanol fractionation method used by the manufacturer (CSL Behring).
- i Limit infusion rate to <3.3 mg IgG/kg per minute (2 mL/kg/h) for 10% solutions.
- j Data on file at Bio Products Laboratory.
- k Maltose does not significantly affect serum glucose or insulin levels and can be safely administered to diabetic patients. Certain BGMS falsely interpret maltose, icodextrin, galactose, and xylose as glucose and can provide falsely elevated glucose readings. If insulin is administered as a result of these readings, hypoglycemia can occur. The BGMS that use test strips containing GDH-PQQ and GDO can provide these false readings. See PI for full details.
- l Under appropriate storage conditions.
- m Must be used within 3 mo after removal from refrigerator to room temperature or less if

- expiration date is shorter.
- n Some infusion rates were converted from those listed in the PI for consistency and reader convenience.
- o Certain severe adverse drug reactions may be related to the rate of infusion. Slowing or stopping the infusion usually allows the symptoms to disappear promptly.
- p Unless specific compatibility information is available, do not mix with other drugs or solutions.
- q Patients at high risk for thromboembolic events include patients who are elderly, overweight, or immobilized; patients with a history of hypertension, cardiovascular disease, or thrombotic disorders; and those who are >65 or dehydrated.
- r Log reduction factor values obtained from those listed in the PI; most are available on respective websites.
- s Data on file at Octapharma.

Table 4. IVIG Infusion Ratesⁿ

IVIG ^a	Initial Infusion Rate	Maintenance Infusion Rate	Maximum Infusion Rate ^o	Comments ^p
Bivigam 10%	0.005 mL/kg/min for 10 min	Increase by 0.48 mL/kg/h every 20 min if tolerated, up to 3.6 mL/kg/h	3.6 mL/kg/h	No filter required; for patients at risk for renal dysfunction or failure, administer at the minimum dose recommended and the minimum infusion rate practicable ^q
Carimune NF 3%-12%	0.48 mL/kg/h	1-2 mL/kg/h	3 mL/kg/h	Reconstitution time is several minutes; no filter required; compatible with NaCl, D5W; increased risk for renal and thrombotic adverse effects ^q
Flebogamma 5% DIF Flebogamma 10% DIF	0.6 mL/kg/h	Increase gradually as tolerated to 6 mL/kg/h (5%), 4.8 mL/kg/h (10%)	6 mL/kg/h (5%), 4.8 mL/kg/h (10%)	No filter required; administer at the minimum infusion rate practical to patients >65 and those at risk for renal failure or thrombotic events ^q
Gammagard Liquid 10%	0.5 mL/kg/h for 30 min (PID)	Increase every 30 min if tolerated, up to 5 mL/kg/h (PID)	5 mL/kg/h (PID)	No filter required; patients at risk for renal dysfunction or thrombotic events should be gradually titrated up to a more conservative maximum rate <2 mL/kg/h ^q
Gammagard S/D 5%	0.5 mL/kg/h for 30 min	Increase gradually as tolerated to 4 mL/kg/h	4 mL/kg/h (5%)	Reconstitution time is <5 min at RT and >20 min if cold; 15-micron filter required and supplied with administration set; compatible with sterile water
Gammaked 10%	0.6 mL/kg/h, 1.2 mL/kg/h (CIDP)	Increase gradually as tolerated to 4.8 mL/kg/h	4.8 mL/kg/h	No filter required; do not dilute with NaCl, but NaCl flush is fine; incompatible with heparin (refer to full PI for details); administer at minimum infusion rate practical to patients >65 or at risk for renal or thrombotic events ^q
Gammaplex 5%	0.6 mL/kg/h, for 15 min	Increase gradually as tolerated every 15 min to 4.8 mL/kg/h	4.8 mL/kg/h	15- to 20-micron in-line filter recommended; ensure that patients with pre-existing renal insufficiency are not volume depleted; discontinue Gammaplex if renal function deteriorates; administer at minimum infusion rate practical to patients at risk for renal dysfunction or thrombotic events ^q
Gamunex-C 10%	0.6 mL/kg/h, 1.2 mL/kg/h (CIDP)	Increase gradually as tolerated to 4.8 mL/kg/h	4.8 mL/kg/h	No filter required; do not dilute with NaCl, but NaCl flush is fine; incompatible with heparin (refer to full PI for details); administer at minimum infusion rate practical to patients >65 or at risk for renal or thrombotic events ^q
Octagam 5%	0.6 mL/kg/h for 30 min	1.2 mL/kg/h for 30 min, then 2.4 mL/kg/h for 30 min, then as tolerated, up to maximum rate	<4.2 mL/kg/h	No filter required or supplied; if an in-line filter is used, the pore size should be 0.2-200 microns; for patients at risk for renal dysfunction or thrombotic events, administer at the minimum infusion rate practical, not to exceed 0.07 mL/kg/min ^q
Octagam 10%	0.01 mL/kg/min for 30 min	Increase gradually as tolerated every 30 min to 0.12 mL/kg/min	≤0.12 mL/kg/min	No filter required or supplied; if an in-line filter is used, the pore size should be 0.2-200 microns; for patients at risk for renal dysfunction or thrombotic events, administer at the minimum infusion rate practical, not to exceed 0.03 mL/kg/min ^q
Privigen 10%	0.3 mL/kg/h	As tolerated, up to maximum recommended rate	2.4 mL/kg/h (ITP), 4.8 mL/kg/h (PID)	No filter required; administer at minimum infusion rate practical to patients at risk for renal dysfunction or thrombotic events ^q

Table 5. Log Reduction Factor Comparisons[†]

Product ^a	Enveloped Viruses				Nonenveloped Virus	TSE (Prion)
	HIV	Models for HCV		Model for Large DNA		
		SBV	BVDV	PRV		
Bivigam 10%	>9.62	>7.11	>11.79	>8.65	5.29 (MEV), 6.18 (BPV), 4.0 (PPV), 7.02 (SV40)	NA
Carimune NF	≥26	≥19	≥9	≥25	≥19 (BEV)	NA
Flebogamma 5% DIF, 10% DIF	≥25.11	≥6.49	≥21.28	≥27.78	≥15.04 (PPV), ≥19.25 (EMCV)	≥11.64
Gammagard Liquid 10%	>14.8	NA	>16.8	>16.9	>5.7 (HAV), >7.7 (EMCV), >5.1 (MMV)	NA
Gammagard S/D 5%	>15 (HIV-1)	NA	>7.5	>9.3	>5.2 (HAV), >5.0 (EMCV), >5.3 (MMV)	NA
Gammaked 10%	≥14	NA	≥16.3	≥12.2	≥5.0 (HAV), 8.2 (PPV)	≥6.6
Gammaplex 5%	>12.9	>20.2	>11.7	NA	>5.9 (HAV), >7.5 (EMCV)	NA
Gamunex-C 10%	≥14	NA	≥16.3	≥12.2	≥5.0 (HAV)	≥6.6
Hizentra 20%	≥16.0	NA	≥11.8	≥17.7	≥9.6 (EMCV), ≥7.8 (MMV)	≥14.8
Hyqvia	>14.8	NA	≥16.8	>16.9	5.7 (HAV), >7.7 (EMCV), 5.1 (MMV)	NA
Octagam 5%	≥14.6	≥16.7	NA	≥16.1	≥9.5 (MEV), ≥7.7 (PPV)	≥6.7 ^s
Octagam 10%	≥14.7	≥20.61	NA	≥18.22	≥20.20 (MEV), ≥6.53 (PPV)	NA
Privigen 10%	≥16.0	NA	≥11.8	≥17.7	≥9.6 (EMCV), ≥7.8 (MMV)	≥14.8

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KEY

BEV bovine enterovirus (RNA model)	HCV hepatitis C virus	NDC National Drug Code
BGMS blood glucose monitoring systems	HH inhibition of hemolysis	NS normal saline
BPV bovine papillomavirus	HIV human immunodeficiency virus	NT neutralization test
BVDV bovine viral diarrhea virus	IFA immunofluorescence assay	PEG polyethylene glycol
CF complement fixation	IgA immune globulin A	PEI Paul Ehrlich Institute International Units
CIDP chronic inflammatory demyelinating polyneuropathy	IgG immune globulin G	PI prescribing information
CLL chronic lymphocytic leukemia	IgM immune globulin M	PID primary immunodeficiency
CMV cytomegalovirus	IQPP International Quality Plasma Program	PPV porcine parvovirus
D5W dextrose 5% in water	ITP idiopathic thrombocytopenic purpura	PRV pseudorabies virus
EIA enzyme immunoassay	IU international unit	RIA radioimmunoassay
EMCV encephalomyocarditis virus (RNA model)	IVIG intravenous immune globulin	RSS reduced space symbology
FDA Food and Drug Administration	KD Kawasaki disease	RT room temperature
GDH glucose dehydrogenase-	MEV mouse encephalomyelitis virus	SBV Sindbis virus
PQQ pyrroloquinolone quinone	MMN multifocal motor neuropathy	SD solvent detergent
GDO glucose-dye-oxidoreductase	MMV mouse minute virus (model for non-lipid DNA virus)	SQ subcutaneous
HAI heterologous anti-immunoglobulin	NA information not available	SV40 simian virus
HAV hepatitis A virus	NaCl sodium chloride	TSE transmissible spongiform encephalopathies
HBV hepatitis B virus		UIN unique identifier number
		VZV varicella zoster virus

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