

Immune Globulins:

Therapeutic, Pharmaceutical,
Cost, and Administration
Considerations

2025

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With financial support from

Kedrion
Biopharma

From the publisher of

PHARMACY PRACTICE NEWS

pharmacypracticenews.com

Specialty Pharmacy
Continuum

specialtypharmacycontinuum.com

With so many immune globulin (IG) products on the market, providers frequently have questions about the best approach to product selection. The charts in this review should help guide pharmacists with that decision.

What is the best approach to IG product selection? Should all the available IG products be considered equivalent and price be the only consideration? Are there special considerations that may be important for individual patients based on their comorbidities? Does the clinical condition of the patient change the selection criteria for the IG product? All of these factors need to be weighed along with the product formulation to match the best product to the patient. Not all IG products are the same, nor are all patients the same. The information in the following charts will help clinicians understand the differences between the several available IG products to make the best treatment decision.

Eight IG products are indicated for SQ use in patients with PID: Hyqvia (Takeda) in a 10% concentration is only for SQ administration; Gammagard Liquid (Takeda), Gammaked (Kedrion), and Gamunex-C (Grifols) come in 10% concentrations for IV or SQ administration; Cutaquig (Octapharma) comes in a 16.5% concentration for SQ administration; and Cuvitru (Takeda), Hizentra (CSL Behring), and Xembify (Grifols) come in 20% concentrations and are indicated for SQ administration. Dosing adjustments are required for all SQ agents when converting from IV.

Cuvitru and Xembify are the only SQ 20% options in the United States to treat adult and pediatric patients with PID that uses glycine as the stabilizer.

Hyqvia is used in combination with recombinant human hyaluronidase (HY). This combination product allows for SQ administration of a large amount of IG product to one site, in a monthly dose that is equivalent to that of IVIG products based on a 1:1 conversion ratio. It is FDA approved for PID in adults and pediatric patients aged 2 years and older. This is the first product of its type. In the chart, it looks identical to Gammagard Liquid 10%, but it is distributed as a dual package with the 5-mL vial of HY. Instructions for administration are unique and specific to this product.

Seven products, Gammagard Liquid, Gammaked, Gamunex-C, Hizentra, Hyqvia, Panzyga (Octapharma), and Privigen (CSL Behring), are approved for use in patients with chronic inflammatory demyelinating

polyneuropathy. Gammagard Liquid is approved to treat multifocal motor neuropathy. Panzyga is approved to treat chronic immune thrombocytopenia in adults. Asceniv 10% (ADMA Biologics) is an IV product approved to treat PID in adults and adolescents (12-17 years of age). It is developed from tailored plasma pools that are derived from at least 1,000 donors with a blend of normal source plasma and hyperimmune RSV plasma. Bivigam 10% (ADMA Biologics) is approved for PID in adults with a recently expanded indication for pediatric patients aged 2 years and older. Alyglo 10% Liquid (GC Biopharma) for IV infusion was approved in 2023 for the treatment of PID in adults. Yimmugo 10% Liquid (Biotest AG) for IV infusion was approved in 2024 for the treatment of PID in patients 2 years of age or older.

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.

Although Tables 1 to 5 may help facilitate these decisions, it is important to understand the clinical effect of changing products. All of the products contain primarily IgG, but 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 osmolarity 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 become evident during the infusion.

The SARS-CoV-2 coronavirus that causes COVID-19 is a large lipid-coated virus that is easily removed in plasma product fractionation by solvent detergent or caprylate utilization, as well as nanofiltration and pasteurization viral inactivation and removal steps. Strict screening of donors for and qualification processes over a 6-month period also serve to protect the plasma supply. Additional information can be found at pptaglobal.org.

(See the PI for each agent for more information about adverse events.)

Dr Siegel reported financial relationships with ADMA Biologics, Kedrion Biopharma, and Takeda.

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Table 1. Therapeutic Considerations

| Product ^a | Manufacturer | FDA-Approved Indications | IgA Content | pH (After Reconstitution) | Plasma Source | Pathogen Inactivation/Removal | Half-Life, d ^b | IgG Subclass, % | | | | 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 | | | | | | | |
| Alyglo 10% Liquid | GC Biopharma Corp www.alyglo.com CS/MI: (833) 426 6426 | PID | ≤100 mcg/mL (<LOQ of 3.9 mcg/mL average) ^d | 4.5-5.5 | Plasma from FDA-approved sites, pooled plasma from not less than 1,000 donors | Cold ethanol, SD, nanofiltration | 3-wk dosing: 20.0±6.0; 4-wk dosing: 29.6±11.0 | 68 | 27 | 4 | 1 | 4.12 IU/mL ^d | NA | NA | 39.7 mcg/mL | NA | NA | Antibody positive | 32.9 IU/g IgG ^d | NA | Type 1: 0.54 (ratio to CBER ref) ^d |
| Asceniv 10% | ADMA Biologics www.admabiologics.com; www.asceniv.com (800) 458-4244 | PID | <LOQ of 43 mcg/mL ^e | 4.0-4.6 | Normal sourced, pooled, and blended with plasma with sufficient titers to RSV neutralizing antibodies and other common respiratory pathogens from not less than 1,000 donors | Precipitation and removal of fraction III during the cold ethanol process, SD, 35-nm nanofiltration, low pH | 3-wk dosing: 28.5±4.4; 4-wk dosing: 39.7±11.6 | 72 | 20 | 6 | 1.9 | 11.33 U/mL | NA | NA | NA | NA | NA | NA | 7 IU/mL | NA | Type 1: 1:1.30 (ratio to CBER 177) |
| Bivigam 10% | ADMA Biologics www.admabiologics.com; www.bivigam.com (800) 458-4244 | PID | <LOQ of 43 mcg/mL ^e | 4.0-4.6 | Pooled plasma from not less than 1,000 donors | Precipitation and removal of fraction III during the cold ethanol process, SD, 35-nm nanofiltration, low pH | 3-wk dosing: 19.6±4.1; 4-wk dosing: 33.5±10.7 | 71 | 21 | 6 | 1.8 | 11.36 U/mL | NA | NA | NA | NA | NA | NA | 8 IU/mL | NA | Type 1: 1:1.09 (ratio to CBER 177) |
| Cutaquig 16.5% | Octapharma USA CS: (866) 766-4860; www.octapharma.com | PID | 206 mcg/mL (average) | 5.0-5.5 | Plasma from FDA-approved sites, pooled plasma from not less than 1,000 donors | Cold ethanol, pH 4.0 incubation, SD | 49.3 (1.8-98.3) | 70 | 25 | 3 | 2 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Cuvitru 20% | Takeda CS: (800) 423-2090; MI: (877) 825-3327 www.takeda.com | PID | 80 mcg/mL (average) | 4.6-5.1 | Plasma from FDA-registered sites | SD, low pH, nanofiltration | 105 (71-119) | 57.6-64.6 | 28.4-34.7 | 3.9-7.0 | 1.8-3.1 | ≥2.4 U/mL | NA | NA | NA | NA | NA | ≥7.0 IU/mL | ≥0.4 IU/mL | NA | NA |
| Flebogamma 5% DIF Flebogamma 10% DIF | Instituto Grifols SA: Barcelona, Spain Grifols Biologicals Inc, Los Angeles, CA CS: (888) GRIFOLS; www.grifols.com | PID ITP (10%) | <50 (5%), <100 (10%) mcg/mL; <3.3 mcg/mL (average) ^{e,f} | 5.6±0.1 ^f | US source IQPP-certified plasma from FDA-registered sites | Pasteurization (60°C, 10 h), SD, 20-nm nanofiltration, fraction I precipitation, fraction II+III incubation, PEG precipitation, acid treatment, TSE removal | 3-wk dosing: 30±9 (5%) 34±10 (10%); 4-wk dosing: 32±5 (5%) 37±13 (10%) | 66.6 | 28.5 (5%) 27.9 (10%) | 2.7 (5%) 3.0 (10%) | 2.2 (5%) 2.5 (10%) | ≥0.61 (4.02 avg) (5%); ≥1.21 (8.03 avg) (10%) U/mL | NA | NA | 0.23 mg/g Ig (5%) 0.22 mg/g Ig (10%) | NA | 10-23 PEI U/mL (5%) 25-45 PEI U/mL (10%) | 264 IU/g Ig (5%) 339.5 IU/g Ig (10%) | ≥2.5 (5%, 10%) (91.8±59.6; 96.2±60.1 avg IU/g Ig) | NA | NA |
| Gammagard Liquid 10% | Takeda CS: (800) 423-2090; MI: (877) 825-3327 www.takeda.com | MMN, PID, CIDP | 37 mcg/mL | 4.6-5.1 | Plasma from FDA-registered sites | SD, low pH, nanofiltration | 35 | 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) |
| Gammagard S/D 5% | Takeda CS: (800) 423-2090; MI: (877) 825-3327 www.takeda.com | CLL, ITP, KD, PID | <1 mcg/mL ^g | 6.4-7.2 | Plasmapheresis, 10,000 donors from FDA-registered sites | SD, cold ethanol fractionation | 37.7±15 | 67 | 25 | 5 | 3 | 2-5 IU/mL (NT); J5 lipid A 1:273 | 17.5 mcg/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) |
| Gammaked 10% | Manufactured by Grifols Therapeutics Inc for Kedrion Biopharma; CS/MI: (855) 353-7466 www.gammaked.com; www.kedrion.com | CIDP, ITP, PID ^h | 46 mcg/mL ^f | 4.0-4.5 ^f | US source IQPP-certified plasma from FDA-registered sites | Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, nanofiltration, low pH incubation, TSE removal | 30-43 | 62.8 | 29.7 | 4.8 | 2.7 | 7.4±1.4 AU/mL | NA | NA | NA | NA | NA | 20±6 IU/mL | 52±15 IU/g IgG | NA | Type 1: 0.88 ±0.34 (ratio to CBER ref) |
| Gammaplex 10% | Manufactured by Bio Products Laboratory Limited, a Kedrion Company; CS/MI: (855) 353-7466 www.gammaplex.com | ITP, PID | <20 mcg/mL | 4.9-5.3 | US source plasma from FDA-registered sites | SD, nanofiltration, terminal low pH incubation | 4-wk dosing: 34.8 | 63.6 | 30.6 | 4.8 | 1 | 16.8 IU/mL | NA | NA | 1,039 U/mL | NA | 759 U/mL | 239 IU/g IgG | 89 IU/g IgG | NA | NA |
| Gamunex-C 10% | Grifols Therapeutics Inc, Research Triangle Park, NC CS: (800) 243-4153; MI: (800) 520-2807 www.gamunex-c.com | CIDP, ITP, PID ^h | 46 mcg/mL ^f | 4.0-4.5 ^f | US source IQPP-certified plasma from FDA-registered sites | Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, nanofiltration, low pH incubation, TSE removal | 30-43 | 62.8 | 29.7 | 4.8 | 2.7 | 7.4±1.4 AU/mL | NA | NA | NA | NA | NA | 20±6 IU/mL | 52±15 IU/g IgG | NA | Type 1: 0.88 ±0.34 (ratio to CBER ref) |
| Hizentra 20%ⁱ | CSL Behring CS: (800) 683-1288; MI: (800) 504-5434 www.cslobehring.com; www.hizentra.com | CIDP maintenance, PID SQ only | ≤50 mcg/mL | 4.6-5.2 | Plasmapheresis, US donors | Cold ethanol, octanoic acid fractionation, anion exchange chromatography, pH 4.0 incubation, 20-nm virus filtration, depth filtration | NA | 69 | 26 | 3 | 2 | 13.5±3.4 (7.2-16.5) IU/mL | NA | NA | NA | 3,337±561 (2,330-4,190) IU/mL | NA | NA | 9.4±2.7 (5.5-16.6) IU/mL | NA | NA |
| Hyqvia (IgG 10% + HY 5%) | Takeda CS: (800) 423-2090; MI: (877) 825-3327 www.takeda.com | CIDP maintenance, PID SQ only | 37 mcg/mL | 4.6-5.1 | Plasma from FDA-registered sites | SD, low pH, nanofiltration | 59.3 | 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) |
| Octagam 5% | Octapharma USA CS: (866) 766-4860; www.octapharma.com | PID | <200 mcg/mL ^j | 5.1-6.0 | Plasma from FDA-approved sites, pooled plasma from not less than 1,000 donors | Cold ethanol, pH 4.0 incubation, SD | 40 | 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) |
| Octagam 10% | Octapharma USA CS: (866) 766-4860; www.octapharma.com | Chronic ITP, Dermatomyositis | 106 mcg/mL | 4.5-5.0 | Plasma from FDA-approved sites, pooled plasma from not less than 1,000 donors | Cold ethanol, pH 4.0 incubation, SD | 36-40 | 65 | 30 | 3 | 2 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Panzyga 10% | Octapharma USA CS: (866) 766-4860; www.octapharma.com | Chronic ITP, CIDP, PID | 100 mcg/mL | 4.5-5.0 | Plasma from FDA-approved sites, pooled plasma from not less than 1,000 donors | Cold ethanol, SD, nanofiltration, ion exchange chromatography after octanoic acid fractionation | 4-wk dosing: 36.1 | 65 | 28 | 3 | 4 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Privigen 10% | CSL Behring CS: (800) 683-1288; MI: (800) 504-5434 www.cslobehring.com; www.privigen.com | Chronic ITP, CIDP, PID | ≤25 mcg/mL | 4.6-5.0 | Plasmapheresis, US donors | Cold ethanol, octanoic acid fractionation, anion exchange chromatography, pH 4.0 incubation, 20-nm virus filtration, depth filtration | 4-wk dosing: 45.4±18.5 in patients with PID | 69 | 26 | 3 | 2 | 6.8 (2.5-14.4) IU/mL | NA | NA | NA | 1,832 (1,050-2,260) IU/mL | NA | NA | 6.2 (2.5-10.9) IU/mL | NA | NA |
| Xembify 20% | Grifols Therapeutics Inc, Research Triangle Park, NC CS: (800) 243-4153; MI: (800) 520-2807 www.xembify.com | PID | 68±19 mcg/mL | 4.1-4.8 | US source IQPP-certified plasma from FDA-registered sites | Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, nanofiltration, low pH incubation, TSE removal | NA | 62 | 30 | 4.3 | 3.2 | 14±4.9 AU/mL | NA | NA | NA | NA | NA | 40±16 IU/mL | 52±16 IU/g IgG | NA | Type 1: 0.93 ±0.18 (ratio to CBER ref) |
| Yimmugo 10% | Manufactured by Biotest AG for Kedrion Biopharma Inc CS/MI: (855)-353-7466; www.yimmugo.us/hcp | PID | ≤300 mcg/mL | 4.4-5.2 | Plasma collected from FDA-licensed facilities | Caprylic acid treatment, low pH, anion exchange chromatography, nanofiltration | 3-wk dosing: 24.8; 4-wk dosing: 29.9 | 63.9 | 30.4 | 4.2 | 1.4 | 10.2 U/mL | NA | NA | NA | 1,611 IU/mL | NA | 1,494 U/mL | 95.9 IU/g | NA | NA |

Table 2. Supply Chain Considerations

| Product ^a | Supply | Distribution | Storage ^k | Return Policy Warranty | Packaging or Labeling Enhancements |
|---|--|----------------------|--|---|---|
| Alyglo 10% Liquid | 5, 10, 20 g | Wholesaler or direct | 2°C-8°C, 36 mo; do not freeze; 8°C-25°C, 24 mo; do not return to refrigeration after storage at RT | Shipping error; defective or damaged product; no out-of-date products | Single-dose, tamper-evident vial containing the labeled amount of functionally active IgG. The components used in packaging are not made with natural rubber latex |
| Asceniv 10% | 5 g | Wholesaler or direct | 2°C-8°C, 36 mo; do not freeze; ≤25°C up to 4 wk within first 24 mo of shelf life; after storage at RT, product must be used or discarded | Shipping error; defective or damaged product; no out-of-date products | Single-use, tamper-evident vial. The components used in the packaging for Asceniv are latex-free |
| Bivigam 10% | 5, 10 g | Wholesaler or direct | 2°C-8°C, 36 mo; do not freeze; ≤25°C up to 4 wk within first 24 mo of shelf life; after storage at RT, product must be used or discarded | Shipping error; defective or damaged product; no out-of-date products | Single-use, tamper-evident vial. The components used in the packaging for Bivigam are latex-free |
| Cutaquig 16.5% | 1, 1.65, 2, 3.3, 4, 8 g | Wholesaler or direct | 2°C-8°C, 36 mo; ≤25°C, 9 mo; do not freeze | Shipping error; defective or damaged product; no out-of-date products | Tamper-evident, latex-free packaging, peel-off label with lot number, expiration date |
| Cuvitru 20% | 1, 2, 4, 8, 10 g | Direct | 2°C-8°C, 36 mo; ≤25°C, 24 mo; do not freeze | Shipping error; defective or damaged product; no out-of-date products | Latex-free packaging, tamper-evident cap, RSS barcode, peel-off label with lot number, expiration date |
| Flebogamma 5% DIF Flebogamma 10% DIF | 0.5, 2.5, 5, 10, 20 g (5%); 5, 10, 20 g (10%) | Wholesaler or direct | 2°C-25°C, 24 mo; do not freeze | 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, not made with natural rubber latex |
| Gammagard Liquid 10% | 1, 2.5, 5, 10, 20, 30 g | Wholesaler or direct | 2°C-8°C, 36 mo; ≤25°C, 24 mo; do not freeze | Shipping error; defective or damaged product; no out-of-date products | Latex-free packaging, tamper-evident cap, RSS barcode, peel-off label with lot number, expiration date |
| Gammagard S/D 5% | 5, 10 g | Wholesaler or direct | ≤25°C, 24 mo; do not freeze | Shipping error; defective or damaged product; no out-of-date products | Tamper-evident cap, peel-off label with lot number, expiration date |
| Gammaked 10% | 1, 2.5, 5, 10, 20 g | Wholesaler | 2°C-8°C, 36 mo; <25°C, 6 mo; do not freeze | 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 |
| Gammplex 10% | 5, 10, 20 g | Wholesaler | 2°C-25°C, 36 mo; do not freeze | Shipping error; defective or damaged product; no out-of-date products | Latex-free, single-use vial, tamper-evident cap, peel-off label with product name and lot number |
| Gamunex-C 10% | 1, 2.5, 5, 10, 20, 40 g | Wholesaler or direct | 2°C-8°C, 36 mo; ≤25°C, 6 mo; do not freeze | 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%ⁱ | PFS: 1, 2, 4, 10 g | Wholesaler | ≤25°C, 30 mo; do not freeze | Shipping error; defective or damaged product; no out-of-date products | Latex-free packaging, peel-off label with lot number, expiration date |
| Hyqvia (IgG 10% + HY 5%) | 2.5, 5, 10, 20, 30 g | Wholesaler or direct | 2°C-8°C, 36 mo; do not freeze ^l | Shipping error; defective or damaged product; no out-of-date products | Latex-free packaging, tamper-evident cap, RSS barcode, peel-off label with lot number, expiration date |
| Octagam 5% | 1, 2.5, 5, 10, 25 g | Wholesaler or direct | 2°C-8°C, 36 mo; ≤25°C, within first 24 mo of shelf life; after storage at ≤25°C, use or discard product | 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, 30 g | Wholesaler or direct | 2°C-8°C, 36 mo; ≤25°C, 9 mo within shelf life; after storage at ≤25°C, use or discard product | Shipping error; defective or damaged product; no out-of-date products | Tamper-evident, latex-free packaging, peel-off label with lot number, expiration date |
| Panzyga 10% | 1, 2.5, 5, 10, 20, 30 g | Wholesaler or direct | 2°C-8°C, 36 mo; ≤25°C, 12 mo; after storage at ≤25°C, product must be used or discarded | 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 | Wholesaler | ≤25°C, 36 mo; do not freeze | Shipping error; defective or damaged product; no out-of-date products | Latex-free, single-use vial, tamper-evident seal, peel-off label with lot number, expiration date |
| Xembify 20% | 1, 2, 4, 10 g | Wholesaler or direct | 2°C-8°C, 36 mo; ≤25°C, 6 mo; after storage at ≤25°C, product must be used or discarded; do not freeze | 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 |
| Yimmugo 10% Liquid | 5, 10, 20 g | Wholesaler or direct | 2°C-8°C, 30 mo; may be stored at RT (more than 8°C and up to 25°C) for a single period not exceeding 6 mo; do not freeze | Shipping error; defective or damaged product; no out-of-date products | No natural latex |

Table 3. Pharmaceutical Considerations

| Product ^a | Available Dosing Forms | Form | Method of Preparation | Gamma Globulin, % | Monomers, % | IgM Content | Albumin | PEG | Sodium Content | Stabilizer | Osmolality/Osmolarity |
|---|--------------------------|-------------|---|--------------------|---|--------------------------------|--------------------------|--|-----------------------------------|---|--|
| Alyglo 10% Liquid | IV | Liquid | Cold ethanol fractionation, depth filtration, anion-exchange chromatography, SD, cation-exchange chromatography, ultrafiltration/diafiltration, nanofiltration (20 nm) | ≥96 | 99.9 monomer + dimers ^d | <LOQ of 15 mcg/mL ^d | NA | NA | No sodium added | Glycine | 240-360 mOsm/kg |
| Asceniv 10% | IV | Liquid | Modified classic Cohn Method 6/Oncley Method 9 fractionation procedure. ^m Precipitation and removal of fraction III of the cold ethanol process, SD, 35-nm nanofiltration, low pH, fractionation with centrifugation | ≥96 | >95 monomers + dimers | ≤80 mcg/mL | ≤2% | NA | 0.100-0.140 M | Glycine | 370-510 mOsm/kg |
| Bivigam 10% | IV | Liquid | Modified classic Cohn Method 6/Oncley Method 9 fractionation procedure. ^m Precipitation and removal of fraction III of the cold ethanol process, SD, 35-nm nanofiltration, low pH, fractionation with centrifugation | ≥96 | >95 monomers + dimers | ≤80 mcg/mL | ≤2% | NA | 0.100-0.140 M | Glycine | 370-510 mOsm/kg |
| Cutaquig 16.5% | SQ | Liquid | Cold ethanol fractionation, ultrafiltration, chromatography, SD, pH 4.0 incubation | ≥96 | ≥94 monomers + dimers | Trace | 0 | 0 | ≤30 mmol/L | Maltose | 310-380 mOsm/kg |
| Cuvitru 20% | SQ | Liquid | Cohn-Oncley, ^m anion-exchange chromatography, SD, nanofiltration, ultrafiltration, low pH incubation | ≥98 | ≥90 monomers + dimers | NA | NA | Not detectable | No sodium added | Glycine | 280-292 mOsm/kg |
| Flebogamma 5% DIF Flebogamma 10% DIF | IV | Liquid | Pasteurization (60°C, 10 h), SD, 20-nm nanofiltration, fraction I precipitation, fraction II+III incubation, PEG precipitation, acid treatment | ≥99 ^{c,f} | ≥95 (100±0 average) (5%); ≥95 (99.9±0.1 average) (10%) monomers + dimers ^{c,f} | Trace | <2 mcg/mL | ≤3 mg/mL (5%) ≤6 mg/mL (10%) monomers + dimers ^{c,f} | Trace (<3.2 mEq/L) ^{c,f} | 5% sorbitol (polyol) | 240-370 mOsm/kg ^{c,f} |
| Gammagard Liquid 10% | IV, SQ (SQ for PID only) | Liquid | Cohn-Oncley, ^m anion-exchange chromatography, SD, nanofiltration, ultrafiltration, low pH incubation | ≥98 | ≥95 monomers + dimers | Trace | NA | Not detectable | No sodium added | Glycine | 240-300 mOsm/kg |
| Gammagard S/D 5% | IV | Lyophilized | Cohn-Oncley, ^m ultrafiltration, SD, anion-exchange chromatography | ≥90 | 96.4 | Trace | <3 mg/mL | <2 mg/mL | 0.85% | 2% glucose, glycine | 636 mOsm/L (5%), 1,250 mOsm/L (10%) ⁿ |
| Gammaked 10% | IV, SQ (SQ for PID only) | Liquid | Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, nanofiltration, low pH incubation | ≥98 | 100 monomers + dimers ^{c,f} | Trace | <2 mcg/mL ^{c,f} | 0 | Trace (<7 mEq/L) ^{c,f} | Glycine | 258 mOsm/kg ^{c,f} |
| Gammaplex 10% | IV | Liquid | Cold ethanol fractionation, ion-exchange chromatography, SD, nanofiltration (20 nm), ultrafiltration/diafiltration, terminal low pH incubation | ≥98 | 99.7-100 monomers + dimers | <0.1 mg/mL | 0 | 0 | ≤5 mM | Glycine | 280-288 mOsm/kg, but not <240 mOsm/kg |
| Gamunex-C 10% | IV, SQ (SQ for PID only) | Liquid | Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, nanofiltration, low pH incubation | ≥98 | 100 monomers + dimers ^{c,f} | Trace | <2 mcg/mL ^{c,f} | 0 | Trace (<7 mEq/L) ^{c,f} | Glycine | 258 mOsm/kg ^{c,f} |
| Hizentra 20%ⁱ | SQ | Liquid | Cold ethanol fractionation, anion-exchange chromatography, octanoic acid fractionation, pH 4.0 incubation, depth filtration, virus filtration, nanofiltration (20 nm) | ≥98 | ≥90 monomers + dimers | NA | NA | NA | Trace | Proline | 380 mOsm/kg |
| Hyqvia (IgG 10% + HY 5%) | SQ | Liquid | Cohn-Oncley, ^m cation- and anion-exchange chromatography, SD, nanofiltration, ultrafiltration, low pH incubation | ≥98 | ≥95 monomers + dimers | Trace | 1 mg/mL | Not detectable | No sodium added | Glycine | 240-300 mOsmol/kg (physiologic range, 285-295 mOsmol/kg) |
| Octagam 5% | IV | Liquid | Cold ethanol fractionation, ultrafiltration, chromatography, SD, pH 4.0 incubation | ≥96 | ≥90 monomers + dimers | ≤0.1 mg/mL | 0 | 0 | ≤30 mmol/L | Maltose ^o (100 mg/mL) | 310-380 mOsm/kg |
| Octagam 10% | IV | Liquid | Cold ethanol fractionation, ultrafiltration, chromatography, SD, pH 4.0 incubation | ≥96 | ≥94 monomers + dimers | <106 mcg/mL | 0 | 0 | ≤30 mmol/L | Maltose ^o (90 mg/mL) | 310-380 mOsm/kg |
| Panzyga 10% | IV | Liquid | Cold ethanol fractionation, ultrafiltration, SD, nanofiltration (20 nm), ion-exchange chromatography | ≥96 | ≥90 monomers + dimers | <0.1 mg/mL | 0 | 0 | Trace | Glycine | 240-310 mOsm/kg |
| Privigen 10% | IV | Liquid | Cold ethanol fractionation, octanoic acid fractionation, anion-exchange chromatography, immunoaffinity chromatography, pH 4.0 incubation, depth filtration, virus filtration, nanofiltration (20 nm) | ≥98 | ≥98 monomers + dimers | NA | Trace | NA | Trace | Proline | 320 mOsmol/kg (range, 240-440 mOsmol/kg) |
| Xembify 20% | SQ | Liquid | Cold ethanol fractionation, caprylate precipitation, depth filtration, low pH incubation, anion-exchange chromatography, nanofiltration | ≥98 | 98-100 monomers + dimers | <0.004 mg/mL | NA | NA | Trace | Glycine and polysorbate 80 | 280-404 mOsm/kg |
| Yimmugo 10% Liquid | IV | Liquid | Cold ethanol fractionation, caprylic acid treatment, anion exchange chromatography, cation exchange chromatography ultrafiltration/diafiltration, nanofiltration, low pH, vibromixing | ≥96 | 92.9 + dimers | Trace | | NA | No sodium added | Glycine (0.27-0.33 mmol/mL); polysorbate 80 (2-20 mcg/mL) | 280-380 mOsm/kg |

Table 4. Log Reduction Factor Comparisons^P

| Product ^a | Enveloped Viruses | | | | | | Nonenveloped Virus | TSE (Prion) |
|---|-------------------|--------|----------------|--------|---------------------|--------|---|-------------------|
| | HIV | WNV | Models for HCV | | Model for Large DNA | B19 | | |
| | | | SBV | BVDV | PRV | | | |
| Alyglo 10% Liquid | ≥14.55 | NA | NA | ≥13.3 | ≥12.41 | NA | ≥8.15 (EMCV), 7.93 (PPV) | NA |
| Asceniv 10% | >9.62 | >4.96 | >7.11 | >11.79 | >8.65 | 6.18 | 5.29 (MEV), 6.18 (BPV), 4.0 (PPV), >7.02 (SV40) | NA |
| Bivigam 10% | >9.62 | >4.96 | >7.11 | >11.79 | >8.65 | 6.18 | 5.29 (MEV), 6.18 (BPV), 4.0 (PPV), >7.02 (SV40) | NA |
| Cutaquig 16.5% | ≥14.07 | | ≥20.61 | | ≥18.22 | | ≥12.20 (MEV), ≥6.53 (PPV) | |
| Cuvitru 20% | >19.9 | >18.3 | | >18.1 | >21.8 | | 9.6 (HAV), >11.9 (EMCV), 10.1 (MMV) | ≥3.2 |
| Flebogamma 5% DIF Flebogamma 10% DIF | ≥25.11 | ≥17.42 | ≥6.49 | ≥21.28 | ≥27.78 | | 15.04 (PPV), ≥19.25 (EMCV) | ≥11.64 |
| Gammagard Liquid 10% | >14.8 | >12.2 | NA | >16.8 | >16.9 | | 5.7 (HAV), >7.7 (EMCV), 5.1 (MMV) | NA |
| Gammagard S/D 5% | >16.8 (HIV-1) | | NA | >8.8 | >10.1 | | >5.2 (HAV), 5.0 (EMCV), >5.3 (MMV) | NA |
| Gammaked 10% | ≥17.7 | ≥9.9 | NA | ≥20.4 | ≥12.2 | | ≥5.0 (HAV), 8.2 (PPV), ≥9.3 (Reo) | ≥6.6 |
| Gammplex 10% | >12.8 | >6.4 | >18.3 | >9.6 | >6.2 | 6.0 | >6.3 (HAV), >8.2 (EMCV), 4.2 (CPV) | >9.4 |
| Gamunex-C 10% | ≥17.7 | ≥9.9 | NA | ≥20.4 | ≥12.2 | | ≥5.0 (HAV), 8.2 (PPV), ≥9.3 (Reo) | ≥6.6 |
| Hizentra 20%ⁱ | ≥17.0 | ≥17.6 | NA | ≥12.7 | ≥17.6 | ≥5.6 | ≥12.0 (EMCV), ≥10.2 (MVM) | |
| Hyqvia (IgG 10% + HY 5%) | >14.8 | >12.2 | NA | >16.8 | >16.9 | 4.8 | 5.7 (HAV), >7.7 (EMCV), 5.1 (MMV) | NA |
| Octagam 5% | ≥14.07 | | ≥20.61 | NA | ≥18.22 | | ≥12.20 (MEV), ≥6.53 (PPV) | ≥6.7 ^a |
| Octagam 10% | ≥14.07 | | ≥20.61 | NA | ≥18.22 | | ≥12.20 (MEV), ≥6.53 (PPV) | NA |
| Panzya 10% | ≥9.37 | | | ≥8.16 | ≥13.16 | | ≥11.66 (MEV), 11.61 (PPV) | ≥10.4 |
| Privigen 10% | ≥17.0 | ≥17.6 | NA | ≥12.7 | ≥17.6 | ≥5.6 | ≥12.0 (EMCV), ≥10.2 (MVM) | |
| Xembify 20% | ≥16.5 | ≥10.4 | ≥6.0 | ≥20.2 | ≥13.0 | | ≥5.0 (HAV), 8.2 (PPV), ≥9.3 (Reo) | ≥6.6 |
| Yimmugo 10% Liquid | ≥16.99 | NA | NA | ≥13.31 | ≥6.21 | ≥12.67 | ≥12.71 (HAV), ≥4.93 (EMCV), 10.34 (PPV), ≥4.96 (HEV) | ≥5.99 |

Table 5. IVIG Infusion Rates[†]

| IVIG ^a | Initial Infusion Rate | Maintenance Infusion Rate | Maximum Infusion Rate ^b | Comments ^c |
|---|---|---|--|--|
| Alyglo 10% Liquid | First: 0.01 mL/kg/min; Second: 0.02 mL/kg/min | First: double every 30 min up to 0.08 mL/kg/min; Second: double every 15 min up to 0.08 mL/kg/min | 0.08 mL/kg/min | For first and second infusions, rates are increased if tolerated |
| Asceniv 10% | 0.3 mL/kg/h for 15 min | Increase gradually every 15 min if tolerated, up to 4.8 mL/kg/h | 4.8 mL/kg/h | Do not dilute; do not mix with other IVIG products or IV medications; if a large dose is required, several vials may be pooled using aseptic technique |
| Bivigam 10% | 0.3 mL/kg/h for 10 min | Increase gradually every 20 min if tolerated by 0.48 mL/kg/h, up to 3.6 mL/kg/h | 3.6 mL/kg/h | Do not dilute; should be infused using a separate line without mixing with other IV fluids or medications; if a large dose is required, several vials may be pooled using aseptic technique |
| Cutaquig 16.5% | ≥17 y: ≤20 mL/h per site; 2-16 y: ≤15 mL/h per site (first 2 infusions) | ≥17 y: maximum of 52 mL/h per site; 2-16 y: maximum of 25 mL/h per site (subsequent infusions) | ≥17 y: 52 mL/h per site; 2-16 y: 25 mL/h per site (subsequent infusions) | Do not dilute; in patients at risk of developing renal dysfunction because of any degree of preexisting renal insufficiency or predisposition to acute renal failure (eg, diabetes mellitus, age >65 y, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs), monitor renal function and consider lower, more frequent dosing |
| Cuvitru 20% | 10-20 mL/h per site | | ≤60 mL/h per site | Infusion rate and volume depends on patient size: patients <40 kg; patients ≥40 kg |
| 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 practicable to patients >65 y and those at risk for renal failure or thrombotic events ^d |
| 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 ^d |
| 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-mcm 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 practicable to patients aged >65 y or at risk for renal or thrombotic events ^d |
| Gammaplex 10% | 0.3 mL/kg/h for 15 min | Increase gradually as tolerated every 15 min to 4.8 mL/kg/h | 4.8 mL/kg/h | No filter required; ensure that patients with preexisting renal insufficiency are not volume depleted; discontinue if renal function deteriorates; for patients at risk for renal dysfunction, thrombotic events, or volume overload, administer at the minimum infusion rate practicable ^d |
| 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 aged >65 y or at risk for renal or thrombotic events ^d |
| 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 in-line filter used, pore size should be 0.2-200 mcm; for patients at risk for renal dysfunction or thrombotic events, administer at the minimum infusion rate practicable, not to exceed 0.07 mL/kg/min ^d |
| Octagam 10% | 0.6 mL/kg/h for 30 min | Increase gradually as tolerated every 30 min to 7.2 mL/kg/h for chronic ITP and 2.4 mL/kg/h for dermatomyositis | 7.2 mL/kg/h (chronic ITP); 2.4 mL/kg/h (dermatomyositis) | No filter required or supplied; if an in-line filter is used, the pore size should be 0.2-200 mcm; for patients at risk for renal dysfunction or thrombotic events, administer at the minimum infusion rate practicable, not to exceed 0.03 mL/kg/min ^d |
| Panzyga 10% | 0.6 mL/kg/h | Increase gradually as tolerated every 15-30 min to 8.4 mL/kg/h (PID), 4.8 mL/kg/h (ITP), and 7.2 mL/kg/h (CIDP) | 8.4 mL/kg/h (PID), 4.8 mL/kg/h (ITP), 7.2 mL/kg/h (CIDP) | Ensure that patients with preexisting renal insufficiency are not volume depleted; discontinue if renal function deteriorates; for patients at risk for renal dysfunction or thrombotic events, administer at the minimum infusion dose and rate practicable |
| Privigen 10% | 0.3 mL/kg/h (CIDP requires loading dose) | Increase gradually as tolerated, up to maximum recommended rate | 2.4 mL/kg/h (ITP), 4.8 mL/kg/h (CIDP, PID) | No filter required; administer at minimum infusion rate practicable to patients at risk for renal dysfunction or thrombotic events ^d ; may be diluted with dextrose injection, USP (D5W); before use, the infusion line may be flushed with dextrose injection, USP (D5W) or 0.9% sodium chloride for injection, USP |
| Xembify 20% | ≥10 y: ≤35 mL/h per site; 2 to <10 y: ≤25 mL/h per site; up to 6 sites | ≥10 y: ≤35 mL/h per site; 2 to <10 y: ≤25 mL/h per site; up to 6 sites | ≥10 y: ≤35 mL/h per site; 2 to <10 y: ≤25 mL/h per site | 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 aged >65 y or at risk for renal or thrombotic events ^d |
| Yimmugo 10% Liquid | 0.3 mL/kg/h for 30 min | Increase every 30 min if tolerated to a maximum of 1.8 mL/kg/h for first infusion; increase every 30 min if tolerated up to maximum rate for subsequent infusions | 7.8 mL/kg/h | No filter required; do not dilute or mix with other IV medications; administer at minimum infusion rate practicable in patients ≥65 y or at risk for renal or thrombotic events |

Key

| | | | |
|-------------|---|-------------|---|
| AU | atomic unit | KD | Kawasaki disease |
| BGMS | blood glucose monitoring systems | LOQ | limit of quantitation |
| BPV | bovine parvovirus | MEV | mouse encephalomyelitis virus |
| BVDV | bovine viral diarrhea virus | MI | medical information |
| B19 | human parvovirus B19 | MMN | multifocal motor neuropathy |
| CBER | Center for Biologics Evaluation and Research | MMV | mouse minute virus (model for nonlipid DNA virus) |
| CIDP | chronic inflammatory demyelinating polyneuropathy | MVM | minute virus of mice |
| CLL | chronic lymphocytic leukemia | NA | not available |
| CMV | cytomegalovirus | NaCl | sodium chloride |
| CPV | canine parvovirus | NDC | National Drug Code |
| CS | customer service | NT | neutralization test |
| D5W | dextrose 5% in water | PEG | polyethylene glycol |
| EIA | enzyme immunoassay | PEI | Paul Ehrlich Institute |
| EMCV | encephalomyocarditis virus (RNA model) | PI | prescribing information |
| GDH- | glucose dehydrogenase- | PID | primary immunodeficiency |
| PQQ | pyrroloquinoline quinone | PFS | prefilled syringes |
| GDO | glucose-dye-oxidoreductase | PPV | porcine parvovirus |
| HAV | hepatitis A virus | PRV | pseudorabies virus |
| HBV | hepatitis B virus | RIA | radioimmunoassay |
| HCV | hepatitis C virus | Reo | reovirus type 3 |
| HEV | hepatitis E virus | RSS | reduced space symbology |
| HH | inhibition of hemolysis | RSV | respiratory syncytial virus |
| HIV | human immunodeficiency virus | RT | room temperature |
| IgA | immune globulin A | SBV | Sindbis virus |
| IgG | immune globulin G | SD | solvent detergent |
| IgM | immune globulin M | SQ | subcutaneous |
| IQPP | International Quality Plasma Program | SV40 | simian virus 40 |
| ITP | idiopathic/immune thrombocytopenic purpura | TSE | transmissible spongiform encephalopathies |
| IU | international unit | UIN | unique identifier number |
| IVIG | intravenous immune globulin | VZV | varicella-zoster virus |
| | | WNV | West Nile virus |

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 Alyglo, characterization study.
- e** Data on file at ADMA Biologics.
- f** Data on file at Grifols.
- g** As of December 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.
- h** DO NOT USE Gammaked or Gamunex-C subcutaneously for ITP or CIDP.
- i** Provided the total weekly dose is maintained for the indication of PID, any dosing interval from daily to biweekly can be used and will result in systemic serum IgG exposure that is comparable to the previous IVIG or weekly Hizentra treatment. For biweekly dosing, multiply the calculated Hizentra weekly dose by 2.
- j** With additional purification steps added in 2010, current release lots contain <100 mcg/mL. Data on file at Octapharma.
- k** Under appropriate storage conditions.
- l** Must be used within 3 mo after removal from refrigerator to RT or less if expiration date is shorter.
- m** 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).
- n** Limit infusion rate to <3.3 mg IgG/kg per min (2 mL/kg/h) for 10% solutions.
- o** 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 the PI for full details.
- p** Log reduction factor values obtained from those listed in the PI; most are available on respective websites.
- q** Data on file at Octapharma.
- r** Some infusion rates were converted from those listed in the PI for consistency and reader convenience.
- s** 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.
- t** Unless specific compatibility information is available, do not mix with other drugs or solutions.
- u** 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 y or dehydrated.