



Medicaid Drug Use Criteria

Immune Globulins

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- Revised June 2020

Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with an asterisk [*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.

Medications listed in the tables and non-FDA approved indications included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

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1 Dosage

1.1 Adults

Immune globulins, solutions comprised primarily of human immunoglobulin (Ig) G with minute concentrations of IgA and IgM, are obtained from pooled plasma from a variety of donors to guarantee a diverse antibody collection with variable antigen-binding sites. Immune globulins work by providing adequate antibody concentrations against an extensive selection of different pathogens.¹⁻⁴ Immune globulins are FDA-approved to manage primary and secondary immunodeficiencies,

prevent infectious diseases, and treat other inflammatory and autoimmune disorders.¹⁻⁶ Hyperimmune globulins like cytomegalovirus immune globulin and varicella zoster immune globulin are prepared from pooled donor serum with high antibody titers to specific infectious organisms and are used to prevent or mitigate the targeted infection.⁷⁻⁸ Immune globulins are administered by the intramuscular, intravenous, or subcutaneous routes.¹⁻⁶ Maximum recommended dosage regimens in adult patients for available immune globulins and hyperimmune globulins are summarized in **Tables 1-3**.

Table 1. Adult Immune Globulin Recommended Dosages: Intramuscular Products^{3, 7, 9}

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|---|---|---|--|
| hepatitis A prophylaxis | immune globulin, human (GamaSTAN® S/D) | 15%-18% protein solution (150 mg/mL to 180 mg/mL), available as 2 mL, 10 mL vials | postexposure prophylaxis (within 14 days of exposure) or pre-exposure prevention for travel for less than 1 month: 0.1 mL/kg as intramuscular (IM) injection travel for 1-2 months: 0.2 mL/kg IM travel for greater than 2 months: repeat 0.2 mL/kg IM dose every 2 months |
| rubella in pregnancy (post-exposure prophylaxis) | immune globulin, human (GamaSTAN® S/D) | | 0.55 mL/kg IM x one dose |
| rubeola (measles) prophylaxis/ modification in immunocompetent patients | immune globulin, human (GamaSTAN® S/D) | | 0.25 mL/kg IM given within 6 days of exposure |
| varicella-zoster modification (passive immunization) | immune globulin, human (GamaSTAN® S/D) | | 0.6 to 1.2 mL/kg x one dose* |
| postexposure varicella prophylaxis in high-risk individuals | varicella-zoster immune globulin (Varizig®) | 125 international units (IU)/1.2 mL | Greater than 40.1kg: 625 IU as IM injection divided between two or more injection sites |

- * if varicella zoster immune globulin not available

Table 2. Adult Immune Globulin Recommended Dosages: Intravenous Products^{1-2, 8, 10-24}

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|---------------------------------------|-----------------------------------|-----------------------|---|
| primary humoral immunodeficiency (PI) | immune globulin, human (Asceniv®) | 100 mg/1 mL | 300 to 800 mg/kg IV every 3-4 weeks; dose to target trough IgG level of 600 mg/dL |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|--|---|----------------------------------|---|
| PI | immune globulin, human (Bivigam®) | 100 mg/1 mL | 300 to 800 mg/kg/dose as IV infusion every 3-4 weeks. (maximum 6 mg/kg/min) |
| PI | immune globulin, human (Carimune® NF) | 6 g single-use vial | 400 to 800 mg/kg/dose as IV infusion every 3 to 4 weeks. (maximum 3 mg/kg/min) |
| chronic idiopathic thrombocytopenic purpura (ITP) | immune globulin, human (Carimune® NF) | | induction: 0.4 g/kg IV on 2 to 5 consecutive days. (maximum 3 mg/kg/min) maintenance: may give an additional dose of 0.4 g/kg after induction therapy if platelet count falls to less than 30,000/mcL or if clinically significant bleeding; for inadequate response, may increase to 0.8 to 1 g/kg as a single dose |
| Prevention of cytomegalovirus disease in heart, kidney, lung, liver and pancreas transplant recipients | cytomegalovirus immune globulin, human (Cytogam®) | 50 mg/mL single-use vial (50 mL) | kidney allograft recipients: 150 mg/kg as IV infusion given within 72 hours after transplant, followed by 100 mg/kg as single IV dose at 2, 4, 6 and 8 weeks posttransplant; 50 mg/kg at weeks 12 and 16 after transplant heart, liver, lung, pancreas allograft recipients: 150 mg/kg as IV infusion given within 72 hours after transplant, followed by 150 mg/kg as single IV dose at 2, 4, 6 and 8 weeks posttransplant; 100 mg/kg at weeks 12 and 16 after transplant |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|--|--|---|---|
| PI | immune globulin, human (Flebogamma® 5% DIF) | 0.5 g, 2.5 g, 5 g, 10 g, 20 g single-use vials | 300 to 600 mg/kg as IV infusion every 3 to 4 weeks. (maximum 5 mg/kg/min) |
| PI | immune globulin, human (Flebogamma® 10% DIF) | | 300 to 600 mg/kg as IV infusion every 3 to 4 weeks. (maximum 8 mg/kg/min) |
| multifocal motor neuropathy | immune globulin, human (Gammagard Liquid®) | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, 30 g protein (100 mg/mL) as single-use bottles | 0.5 to 2.4 g/kg/month as IV infusion based on clinical response |
| PI | immune globulin, human (Gammagard Liquid®) | | 300 to 600 mg/kg as IV infusion every 3 to 4 weeks. (maximum 8 mg/kg/min) |
| ITP | immune globulin (Gammagard S/D®) | 5 g, 10 g freeze-dried IgG in single-use bottle (IgA concentrations less than 1 µ/mL) | 1 g/kg as single dose as IV infusion; two additional doses may be given on alternate days if needed based on clinical response and platelet count |
| Kawasaki disease | immune globulin (Gammagard S/D®) | | 1 g/kg as single dose or 400 mg/kg/day x 4 consecutive days within 7 days of fever onset in conjunction with appropriate aspirin therapy (80-100 mg/kg/day in four divided doses) |
| hypogammaglobulinemia and/or recurrent bacterial infections due to B-cell chronic lymphocytic leukemia | immune globulin, human (Gammagard S/D®) | | 400 mg/kg as IV infusion every 3 to 4 weeks |
| PI | immune globulin, human (Gammagard S/D®) | | 300 to 600 mg/kg as IV infusion every 3 to 4 weeks. (maximum 4 mL/kg/hr) |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|--|---|---|--|
| chronic ITP | immune globulin, human [Gammaked® 10% (sucrose-free)] | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, single-use vials | 2 g/kg in two divided doses (1 g/kg) over two consecutive days, or five divided doses (0.4 g/kg) over five consecutive days [^] . (maximum 8 mg/kg/min) |
| chronic inflammatory demyelinating polyneuropathy (CIDP) | immune globulin, human [Gammaked® 10% (sucrose-free)] | | 2 g/kg as IV loading dose in divided doses over 2-4 consecutive days followed by 1 g/kg IV maintenance dose as single dose or two divided doses (0.5 g/kg) over two consecutive days every 3 weeks |
| PI | immune globulin, human [Gammaked® 10% (sucrose-free)] | | 300 to 600 mg/kg as IV infusion every 3 to 4 weeks. (maximum 8 mg/kg/min) |
| chronic ITP | immune globulin, human (Gammaplex® 5%) | 5% solution (50 mg/mL): 5 g, 10 g, 20 g single-use glass bottles | 1 g/kg daily as IV infusion for 2 consecutive days. (maximum 4 mg/kg/min) |
| PI | immune globulin, human (Gammaplex® 5%) | | 300 to 800 mg/kg as IV infusion every 3 to 4 weeks. (maximum 4 mg/kg/min) |
| chronic ITP | immune globulin, human (Gammaplex® 10%) | 10% solution (100 mg/mL): 5 g, 10 g, 20 g single-use glass bottles | 1 g/kg daily as IV infusion for 2 consecutive days. (maximum 8 mg/kg/min) |
| PI | immune globulin, human (Gammaplex® 10%) | | 300 to 800 mg/kg as IV infusion every 3 to 4 weeks. (maximum 8 mg/kg/min) |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|---|---------------------------------------|--|--|
| CIDP | immune globulin, human (Gamunex®-C) | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, 40 g protein single use vials | 2 g/kg as IV loading dose in divided doses over 2-4 consecutive days followed by 1 g/kg IV maintenance dose as single dose or two divided doses (0.5 g/kg) over two consecutive days every 3 weeks |
| idiopathic thrombocytopenic purpura (ITP) | immune globulin, human (Gamunex®-C) | | 2 g/kg in two divided doses (1 g/kg) over two consecutive days, or five divided doses (0.4 g/kg) over five consecutive days [^] . (maximum 8 mg/kg/min) |
| PI | immune globulin, human (Gamunex®-C) | | 300 mg/kg to 600 mg/kg every 3-4 weeks. (maximum 8 mg/kg/min) |
| PI | immune globulin, human (Octagam® 5%) | 1 g, 2.5 g, 5 g, 10 g, 25 g single use vials | 300 to 600 mg/kg as IV infusion every 3 to 4 weeks |
| chronic ITP | immune globulin, human (Octagam® 10%) | 2 g, 5 g, 10 g, 20g, 30 g single use vials | 2 g/kg IV as total dose, given as two 1 g/kg IV doses on 2 consecutive days. (maximum 12 mg/kg/min) |
| chronic ITP | immune globulin, human (Panzyga®) | 100 mg/1 mL | 1 g/kg (10 mL/kg) IV daily given on 2 consecutive days |
| PI | immune globulin, human (Panzyga®) | | 300-600 mg/kg (3 to 6 mL/kg) IV every 3 to 4 weeks; adjust dose to achieve desired clinical response and trough IgG levels |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|----------------------|------------------------------------|---|--|
| CIDP | immune globulin, human (Privigen®) | 0.1 g/mL single use vials (50 mL, 100 mL, 200 mL, 400 mL) | 2 g/kg as loading dose in divided doses over 2-5 consecutive days followed by 1 g/kg maintenance dose as single dose or two divided doses (0.5 g/kg) over two consecutive days every 3 weeks |
| ITP | immune globulin, human (Privigen®) | | 1 g/kg IV daily for two consecutive days. (maximum 4 mg/kg/min) |
| PI | immune globulin, human (Privigen®) | | 200 to 800 mg/kg IV every 3 to 4 weeks; adjust dose based on clinical response and serum IgG trough levels. (maximum 8 mg/kg/min) |

- ^ if platelet counts return to normal after first 1 g/kg dose, the second 1g/kg dose does not need to be administered

Table 3. Adult Immune Globulin Recommended Dosages: Subcutaneous Products¹,
9-29

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|---------------------------------------|------------------------------------|--------------------------|--|
| Primary humoral immunodeficiency (PI) | immune globulin, human (Cutaquig®) | 165 mg/1 mL | for patients receiving IVIG for at least 3 months, dose based off previous IVIG dose in grams divided by the number of weeks between IVIG doses, then multiply by 1.4; begin one week after last IVIG dose## |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|--|---|---|---|
| PI | immune globulin, human (Cuvitru®) | 200 mg/mL (20%) single use vials | dose based on previous IVIG or Hyqvia® dose in grams divided by weeks treated with previous immune globulin x 1.3 and administered weekly or every two weeks; based on clinical response and serum IgG trough levels+ |
| PI | immune globulin, human (Gammagard Liquid®) | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, 30 g protein (100 mg/mL) as single-use bottles | begin one week after last IVIG infusion; dose based on previous IVIG dose in grams x 1.37 divided by number of weeks between doses; dosages based on clinical response and serum IgG trough levels^^ |
| PI | immune globulin, human [Gammaked® 10% (sucrose-free)] | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, single-use vials | begin one week after last IVIG infusion; dose based on previous IVIG dose in grams x 1.37 divided by number of weeks between doses; dosages based on clinical response and serum IgG trough levels++ |
| PI | immune globulin, human (Gamunex®-C) | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, 40 g protein single use vial | SC dose based on previous IVIG dose in grams x 1.37 divided by number of weeks between doses; based on clinical response and serum IgG trough levels# |
| chronic inflammatory demyelinating polyneuropathy (CIDP) | immune globulin, human (Hizentra®) | 0.2 g/mL single-use vial (5 mL, 10 mL, 20 mL, 50 mL) | begin 1 week after last IVIG infusion; 0.4 g/kg/week SC given in 1 or 2 sessions over 1 to 2 consecutive days |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|----------------------|---|--------------------------|--|
| PI | immune globulin, human (Hizentra®) | | may be given after patient has received IVIG for at least 3 months; SC dose based on previous IVIG dose in grams divided by number of weeks between doses x 1.37 and administered weekly or every two weeks; based on clinical response and serum IgG trough levels@ |
| PI | immune globulin, human with recombinant human hyaluronidase (Hyqvia®) | | patients switching from previous IVIG treatment: administer same dose and frequency as previous IVIG treatment as SC doses, after initial SC dose ramp-up** treatment-naïve patients: 300 to 600 mg/kg every 3 to 4 weeks SC, after initial SC dose ramp-up** |
| PI | immune globulin, human (Xembify®) | 200 mg/1 mL | patients switching from previous IVIG treatment: divide the previous monthly IVIG dose in grams by the number of weeks between IVIG doses, then multiply by 1.37@@ |

- ##consult Cutaquig® package insert for specific SC dosage requirements
- +consult Cuvitru® package insert for specific SC dosage requirements
- #consult Gamunex® - C package insert for specific SC dosage requirements
- @consult Hizentra® package insert for specific SC dosage requirements
- **Hyqvia® dose ramp-up requires graduated dose increase over 3 to 4 weeks to targeted dose
- ++consult Gammaked® package insert for specific SC dosage requirements
- ^^ consult Gammagard Liquid® package insert for specific SC dosage requirements
- @@ consult Xembify® package insert for specific SC dosage requirementsPediatrics

Select immune globulins are FDA-approved for use in pediatric patients to manage immune thrombocytopenic purpura and primary immunodeficiencies.^{1, 6, 30} Pediatric safety and efficacy have not yet been established for Hyqvia®.^{12, 23} Varicella zoster immune globulin is indicated for use in pediatric patients at high risk for adverse outcomes following exposure to chickenpox or herpes zoster.⁹ Maximum recommended dosages for pediatric patients are summarized in **Tables 4-6**.

Table 4. Pediatric Immune Globulin Recommended Dosages: Intramuscular Products^{3, 7}

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|---|---|-------------------------------------|---|
| postexposure varicella prophylaxis in high-risk individuals | varicella-zoster immune globulin (Varizig®) | 125 international units (IU)/1.2 mL | <p>Less than or equal to 2 kg: 62.5 IU 2.1 to 10 kg: 125 IU 10.1 to 20 kg: 250 IU 20.1 to 30 kg: 375 IU 30.1 to 40 kg: 500 IU Greater than 40.1kg: 625 IU</p> <p>all doses given as IM injection; divide between two or more injection sites if injection volume greater than 3 mL</p> |

Table 5. Pediatric Immune Globulin Recommended Dosages: Intravenous Products^{1-2, 8, 10-24}

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|---------------------------------------|-----------------------------------|-----------------------|---|
| Primary humoral immunodeficiency (PI) | Immune globulin, human (Asceniv®) | 100 mg/1 mL | 12 to 17 years: 300 to 800 mg/kg every 3 to 4 weeks; target IgG trough levels of greater than or equal to 600 mg/dL |
| PI | immune globulin, human (Bivigam®) | 100 mg/1 mL | 6 years and older: 300 to 800 mg/kg/dose as IV infusion every 3-4 weeks. (maximum 6 mg/kg/min) |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|--|---|---|--|
| | | | acute: 0.4 g/kg as IV infusion on 2-5 consecutive days |
| idiopathic/immune thrombocytopenic purpura (ITP) | immune globulin, human (Carimune® NF) | 6 g single-use vial | chronic ITP (if platelet count decreases to less than 30,000/ μ L after acute induction therapy): 800 mg/kg/dose to 1 g/kg as single IV infusion. (maximum 3 mg/kg/min) |
| PI | immune globulin, human (Carimune® NF) | | Less than 18 years: 400 to 800 mg/kg/dose as IV infusion every 3 to 4 weeks. (maximum 3 mg/kg/min) |
| PI | immune globulin, human (Flebogamma® 5% DIF) | 0.5 g, 2.5 g, 5 g, 10 g, 20 g single-use vials | Less than 18 years: 300 to 600 mg/kg as IV infusion every 3 to 4 weeks. (maximum 5 mg/kg/min) |
| PI | immune globulin, human (Gammagard Liquid®) | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, 30 g protein (100 mg/mL) as single-use bottles | 2 years to less than 18 years: 300 to 600 mg/kg as IV infusion every 3 to 4 weeks. (maximum 8 mg/kg/min) |
| Kawasaki disease | immune globulin (Gammagard S/D®) | 5% solution: IV powder for solution 5 g, 10 g | 1 g/kg as single dose or 400 mg/kg/day x 4 consecutive days within 7 days of fever onset (MAX rate of 4 mL/kg/hr) in conjunction with appropriate aspirin therapy (80-100 mg/kg/day in four divided doses) |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|----------------------|---|--|--|
| chronic ITP | immune globulin, human [Gammaked® 10% (sucrose-free)] | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, single-use vials | 2 g/kg in two divided doses (1 g/kg) over two consecutive days, or five divided doses (0.4 g/kg) over five consecutive days [^] . (maximum 8 mg/kg/min) |
| PI | immune globulin, human [Gammaked® 10% (sucrose-free)] | | 2 years to less than 18 years: 300 to 600 mg/kg as IV infusion every 3 to 4 weeks. (maximum 8 mg/kg/min) |
| PI | immune globulin, human (Gammaplex® 5%) | 5% solution (50 mg/mL): 5 g, 10 g, 20 g single-use glass bottles | 2 years to less than 18 years: 300 to 800 mg/kg as IV infusion every 3 to 4 weeks. (maximum 4 mg/kg/min) |
| ITP | immune globulin, human (Gamunex®-C) | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, 40 g protein single-use vials | 2 g/kg in two divided doses (1 g/kg) over two consecutive days, or five divided doses (0.4 g/kg) over five consecutive days [^] . (maximum 8 mg/kg/min) |
| PI | immune globulin, human (Gamunex®-C) | | 2 years to less than 18 years: 300 mg/kg to 600 mg/kg every 3-4 weeks. (maximum 8 mg/kg/min) |
| PI | immune globulin, human (Octagam® 5%) | 1 g, 2.5 g, 5 g, 10 g, 25 g single use vials | 6 years to less than 18 years: 300 to 600 mg/kg as IV infusion every 3 to 4 weeks |
| PI | immune globulin, human (Panzyga®) | 100 mg/1 mL | 2 years to less than 18 years: 300-600 mg/kg (3-6 mL/kg) IV every 3 to 4 weeks; adjust dose to achieve desired clinical response and trough IgG levels |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|----------------------|------------------------------------|---|--|
| chronic ITP | immune globulin, human (Privigen®) | 0.1 g/mL single use vials (50 mL, 100 mL, 200 mL, 400 mL) | 15 years to 17 years: 1 g/kg IV daily for two consecutive days. (maximum 4 mg/kg/min) |
| PI | immune globulin, human (Privigen®) | | 3 years to less than 18 years: 200 to 800 mg/kg IV every 3 to 4 weeks; adjust dose based on clinical response and serum IgG trough levels. (maximum 8 mg/kg/min) |

- ^ if platelet counts return to normal after first 1 g/kg dose, the second 1g/kg dose does not need to be administered

Table 6. Pediatric Immune Globulin Recommended Dosages: Subcutaneous Products^{1, 9-29}

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|----------------------|--|---|--|
| PI | immune globulin, human (Cuvitru®) | 200 mg/mL (20%) single-use vials (5 mL, 10 mL, 20 mL, 40 mL) | 2 years to less than 18 years: dose based on previous IVIG or Hyqvia® dose in grams divided by weeks treated with previous immune globulin x 1.3 and administered weekly or every two weeks; based on clinical response and serum IgG trough levels+ |
| PI | immune globulin, human (Gammagard Liquid®) | 1 g protein, 2.5 g protein, 5 g protein, 10 g protein, 20 g protein, 30 g protein (100 mg/mL) as single-use bottles | 2 years to less than 18 years: SC dose based on previous IVIG dose x 1.37 divided by number of weeks between doses; dosage adjustments based on clinical response and serum IgG trough levels# |

| Treatment Indication | Drug Name | Dosage Form/ Strength | Maximum Recommended Dosage |
|----------------------|------------------------------------|--|--|
| PI | immune globulin, human (Hizentra®) | 0.2 g/mL single-use vial (5 mL, 10 mL, 20 mL, 50 mL) | 2 years to less than 18 years: may be given after patient has received IVIG for at least 3 months; dose based on previous IVIG dose in grams divided by number of weeks between doses x 1.37 and administered weekly or every two weeks; based on clinical response and serum IgG trough levels@ |
| PI | immune globulin, human (Xembify®) | 200 mg/1 mL | 2 years to less than 18 years: for patients already receiving IVIG. Divid previous monthly IVIG dose in grams by the number of weeks between IVIG doses, then multiply by 1.37@@ |

- # consult Gamunex® - C package insert for specific SC dosage requirements
- + consult Cuvitru® package insert for specific SC dosage requirements
- @consult Hizentra® package insert for specific SC dosage requirements
- @@consult Xembify® package insert for specific SC dosage requirement

2 Duration of Therapy

Immune globulins, when used to manage primary immunodeficiency, may be continued indefinitely as primary immunodeficiency is a chronic, lifelong disease.⁴ Patients diagnosed with idiopathic thrombocytopenic purpura, an autoimmune disorder characterized by platelet destruction, may require immune globulin therapy to increase platelet counts. Immune globulin therapy is typically required for only 24-48 hours to stabilize platelet counts, but patients may require repeat courses of immune globulin therapy as ITP can be a chronic, lifelong condition.³¹ GamaSTAN® S/D, an immune globulin approved for use to prevent hepatitis A, measles, and varicella viral infections, is typically administered as a one-time dose;

individuals travelling for a prolonged time period (greater than 2 months) to areas where hepatitis A is prevalent should receive repeat doses every two months.^{5, 9} Cytomegalovirus immune globulin (Cytogam®) is administered at an every 2- or 4-week dosing interval through week 16 following organ transplant.⁸ Varicella zoster immune globulin (Varizig®) is administered as a one-time dose to individuals at high risk of developing varicella post exposure (e.g., immunocompromised patients, neonates and infants less than 1 year of age, pregnant women). Patients re-exposed to varicella at least 3 weeks after initial administration may require a second dose.⁷

3 Duplicative Therapy

Concurrent administration of multiple immune globulins does not provide additional therapeutic benefit and is not recommended. However, adjunctive administration of an immune globulin and a hyperimmune globulin could potentially be necessary in certain circumstances. Patient profiles containing concomitant prescriptions for two or more immune globulin products will be reviewed.

4 Drug-Drug Interactions

Patient profiles will be assessed to identify those drug regimens which may result in clinically significant drug-drug interactions. The following drug-drug interactions are considered clinically relevant for immune globulins. Only those drug-drug interactions classified as clinical significance level 1 or those considered life-threatening which have not yet been classified will be reviewed.

4.1 Live/Live Attenuated Virus Vaccines^{1, 6}

(e.g., measles, mumps, rubella, varicella) [clinical significance level- major (DrugReax); 2-major (CP)]

Adjunctive administration of immune globulins with live/live attenuated virus vaccines may inhibit the immune response to the vaccination by passively transferring antibodies and diminishing the desired vaccine effect. Antibodies present in immune globulins may diminish the response to mumps, rubella, and

varicella vaccines for up to 6 months, while the measles vaccine response may be compromised for up to one year or more. Do not administer live vaccines for at least three months after immune globulin administration. Immune globulin and the hyperimmune globulin, varicella zoster immune globulin, should not be administered concurrently with the live varicella zoster vaccine. There should be at least a five-month interval between immune globulin (including varicella zoster immune globulin) administration and live varicella vaccination. Immune globulin should not be administered for two months after live varicella vaccine administration unless the benefits of immune globulin administration outweigh the potential for reduced vaccine effects.

5 References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc; 2020. Available at: <http://www.clinicalpharmacology.com>. Accessed May 13, 2020.
2. Ballow M, Shehata N. Overview of intravenous immune globulin (IVIg) therapy. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on May 27, 2020.)
3. Jolles S. Subcutaneous and intramuscular immune globulin therapy. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on May 27, 2020.)
4. Bonilla FA. Primary immunodeficiency: Overview of management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on May 27, 2020.)
5. Facts & Comparisons eAnswers, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2020; May 13, 2020.
6. IBM Micromedex® DRUGDEX® (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com.libproxy.uthscsa.edu/> (cited: May 13, 2020).
7. Varicella zoster immune globulin - human (Varizig®) package insert. Aptevo BioTherapeutics LLC, June 2018.
8. Cytomegalovirus immune globulin intravenous – human (Cytogam®) package insert. CSL Behring LLC, November 2017.
9. Immune globulin – human (GamaSTAN® S/D) package insert. Grifols Therapeutics Inc., February 2018.

10. Immune globulin intravenous- human-sira (Asceniv®) package insert. ADMA Biologics, Inc., April 2019.
11. Immune globulin intravenous- human (Bivigam®) package insert. ADMA Biologics, Inc., July 2019.
12. Immune globulin intravenous nanofiltered – human (Carimune® NF) package insert. CSL Behring LLC, May 2018.
13. Immune globulin intravenous 5% - human (Flebogamma® 5% DIF) package insert. Grifols, September 2019.
14. Immune globulin intravenous 10% - human (Flebogamma® 10% DIF) package insert. Grifols, September 2019.
15. Immune globulin infusion 10% solution – human (Gammagard Liquid®) package insert. Baxalta US Inc., June 2016.
16. Immune globulin intravenous, solvent detergent treated – human with IgA concentrations less than 1 µg/mL (Gammagard S/D®) package insert. Baxalta US Inc., November 2018.
17. Immune globulin injection 10% - human (Gammaked™) package insert. Grifols Therapeutics Inc., June 2018.
18. Immune globulin intravenous, 5% liquid – human (Gammaplex 5%®) package insert. BPL Inc., September 2019.
19. Immune globulin intravenous, 10% liquid – human (Gammaplex 10%®) package insert. BPL Inc., September 2019.
20. Immune globulin injection – human (Gammunex®-C) package insert. Grifols Therapeutics Inc., January 2020.
21. Immune globulin intravenous 5% - human (Octagam® 5%) package insert. Octapharma USA Inc., September 2019.
22. Immune globulin intravenous 10% - human (Octagam® 10%) package insert. Octapharma USA Inc., August 2018.
23. Immune globulin intravenous- human-ifas (Panzyga®) package insert. Pfizer Labs, February 2020.
24. Immune globulin intravenous 10% liquid – human (Privigen®) package insert. CSL Behring LLC, March 2019.
25. Immune globulin subcutaneous- human-hipp (Cutiquig®) package insert. Octapharma USA Inc., November 2019.
26. Immune globulin subcutaneous – human (Cuvitru®) package insert. Shire US Inc., June 2018.
27. Immune globulin subcutaneous – human (Hizentra®) package insert. CSL Behring LLC, March 2020.
28. Immune globulin infusion 10% - human, with recombinant human hyaluronidase (Hyqvia®) package insert. Shire US Inc., February 2020.

29. Immune globulin subcutaneous- human-klhw (Xembify®) package insert. Grifols Therapeutics Inc., July 2019.
30. South M, Isaacs D, eds. Practical pediatrics. 7th ed. Philadelphia, PA: Elsevier; 2012. ClinicalKey website. <https://www-clinicalkey-com.libproxy.uthscsa.edu/#!/>. Accessed June 2, 2020.
31. Arnold DM. Immune thrombocytopenia (ITP) in adults: Initial treatment and prognosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on May 27, 2020.)