Clinical Policy: Immune Globulins

Reference Number: CP.PHAR.103
Effective Date: 08/12
Last Review Date: 09/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are immune globulin (IG) products requiring prior authorization: Bivigam™, Carimune® NF, Cuvitru™, Cytogam®, Flebogamma® DIF (5%), Flebogamma® DIF (10%), GamaSTAN® S/D, Gammagard® Liquid, Gammagard® S/D, Gammaked™, Gammaplex®, Gamunex®-C, Hizentra®, Hyqvia®, Octagam® 5%, Octagam® 10%, Privigen®.

FDA Approved Indication(s)

Immunoblobulin (IG) products identified in this policy are approved for the following uses *(see Appendix B below for individual products by route and indication):*

- Immune globulin (intravenous route) (IVIG) formulations:
  - Primary humoral immunodeficiency: for replacement therapy.*
  - Immune thrombocytopenic purpura (ITP) (acute/chronic): Treatment to raise platelet counts, including to prevent bleeding or allow surgery. **
  - Chronic inflammatory demyelinating polyneuropathy (CIDP): Treatment to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.
  - Kawasaki syndrome: Prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients (administered concurrently with aspirin).
  - Multifocal motor neuropathy (MMN): Maintenance therapy to improve muscle strength and disability in adult patients.
  - B-cell chronic lymphocytic leukemia (CLL): Prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell CLL.
  - Cytomegalovirus (CMV): Prophylaxis of CMV disease associated with transplantation of kidney, lung, liver, pancreas, heart. In transplants of these organs (other than kidney) from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir.
- Immune globulin (subcutaneous route) (SCIG) formulations:
  - Primary humoral immunodeficiency: for replacement therapy.
- Immune globulin (intramuscular route)(IMIG) formulations:
  - Hepatitis A: The prophylactic value of GamaSTAN S/D is greatest when given before or soon after exposure to hepatitis A. GamaSTAN S/D is not indicated in persons with clinical manifestations of hepatitis A or in those exposed >2 weeks previously.
  - Measles (rubeola): To prevent or modify measles give GamaSTAN S/D in a susceptible person exposed <6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. GamaSTAN S/D may be especially indicated for susceptible household contacts of measles patients, particularly contacts <1 year of age, for whom the risk of complications is highest. GamaSTAN S/D and measles vaccine should not be given at the same time. If a child is >12 months and has received

GamaSTAN S/D, he should be given measles vaccine about 3 months later when the measles antibody titer will have disappeared. If a susceptible child exposed to measles is immunocompromised, GamaSTAN S/D should be given immediately. Do not administer measles vaccine or any other live viral vaccine to children who are immunocompromised.

- Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella-Zoster Immune Globulin – human (VZIG). If VZIG is unavailable, GamaSTAN S/D, promptly given, may also modify varicella.
- Rubella: The *routine use* of GamaSTAN S/D for prophylaxis of rubella in early pregnancy is of dubious value and cannot be justified. Some studies suggest that the use of GamaSTAN S/D in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, GamaSTAN S/D may benefit those women who will not consider a therapeutic abortion. *[For more information, see CDC Control and Prevention of Rubella: Evaluation and Management of Suspected Outbreaks, Rubella in pregnant women, and surveillance for congenital rubella syndrome. MMWR Recomm Rep. 2001; 50(RR-12):1-23.]*

**Primary humoral immunodeficiency: Labeled indications specifying age differ across products; information common to all products is notated.*
***ITP: Labeled indications specifying acute versus chronic ITP, and age, differ across products; information common to all products is notated.*

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that the immune globulin products referenced above are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Intravenous Immune Globulin Formulations (must meet all)**:**

1. Request for IVIG applies to one of the following diagnoses/indications:
   a. Primary humoral immunodeficiency, including but not limited to congenital agammaglobulinemia, common variable immunodeficiency [CVID], X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, severe combined immunodeficiencies, (i and ii):
      i. One of the following IG products is requested: Bivigam, Carimune NF, Flebogamma DIF (5%/10%), Gammagard Liquid or S/D, Gammaked, Gammaplex, Gamunex-C (preferred), Octagam (5%), Privigen;
      ii. If request is not for Gamunex-C, member must have contraindication or clinically significant adverse effects to Gamunex-C;
   b. Immune (idiopathic) thrombocytopenic purpura (ITP) (i and ii):
      i. One of the following IG products is requested: Carimune NF, Flebogamma DIF (10%), Gammagard S/D, Gammaked, Gammaplex, Gamunex-C (preferred), Octagam (10%), Privigen;
      ii. If request is not for Gamunex-C, member must have contraindication or clinically significant adverse effects to Gamunex-C;

c. Chronic inflammatory demyelinating polyneuropathy (CIDP) (i and ii):
   i. One of the following IG products is requested: Gammaked, Gamunex-C (preferred);
   ii. If request is not for Gamunex-C, member must have contraindication or clinically significant adverse effects to Gamunex-C;
d. Kawasaki syndrome (i and ii):
   i. Gammagard S/D is requested;
   ii. Treatment plan includes aspirin therapy;
e. Multifocal motor neuropathy (MMN):
   i. Gammagard Liquid is requested;
f. B-cell chronic lymphocytic leukemia (CLL) (i and ii):
   i. Gammagard S/D is requested for bacterial infection prophylaxis;
   ii. Pretreatment hypogammaglobulinemia (serum IgG < 500 mg/dl) or history of recurrent bacterial infections;
g. Cytomegalovirus (CMV):
   i. Cytogam is requested for prophylaxis of CMV disease associated with transplantation of kidney, lung, liver, pancreas or heart.

Approval duration: 6 months

B. Subcutaneous Immune Globulin Formulations (must meet all)**:**

1. Request for SCIG applies to the following diagnosis/indication:
   a. Primary humoral immunodeficiency, including but not limited to congenital agammaglobulinemia, CVID, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, severe combined immunodeficiencies (i and ii):
      i. One of the following IG products is requested : Cuvitru, Gammagard Liquid, Gammaked, Gamunex-C (preferred), Hizentra, Hyqvia;
      ii. If request is not for Gamunex-C, member must have contraindication or clinically significant adverse effects to Gamunex-C;
2. IG will be administered in a controlled healthcare setting or the treatment plan provides for management of a potential acute hypersensitivity reaction.

Approval duration: 6 months

C. Intramuscular Immune Globulin Formulations (must meet all)**:**

1. Request for intramuscular (IM) GamaSTAN S/D for one of the following indications:
   a. Hepatitis A post-exposure/high-risk prophylaxis (i and ii):
      i. Hepatitis A exposure or at high risk for exposure as follows (a or b):
         a) Exposure to hepatitis A in the past 2 weeks (e.g., household contact, sexual contact, sharing illicit drugs with someone positive for hepatitis A, regular babysitters/caretakers, food handlers at the same establishment as one who is positive for hepatitis A) AND does not have clinical manifestations of hepatitis A;
         b) Traveling to or working in an area endemic for hepatitis A;
      ii. Meets any of the following (a, b or c):
         a) Hepatitis A vaccine is locally unavailable;
         b) History of severe allergic reaction (anaphylaxis) to the hepatitis A vaccine;

c) If either exposed to the virus or traveling in ≤ 2 weeks to an area endemic for hepatitis A, then (1, 2 or 3):
1) Age < 1 year or > 40 years;
2) Chronic liver disease or other chronic medical condition;
3) Immunocompromised;

b. Measles (rubeola) post-exposure prophylaxis (i, ii and iii):
i. Exposure to measles within the past 6 days;
ii. Member has not previously received a measles vaccine AND has not previously had measles;
iii. Meets any of the following (any a - f):
a) Measles vaccine is locally unavailable;
b) History of severe allergic reaction (anaphylaxis) to the measles vaccine;
c) Pregnancy;
d) Immunocompromised;
e) Has been >3 days since exposure;
f) Age <12 months;

c. Chickenpox (varicella) post-exposure prophylaxis (all i - iv):
i. Recent exposure varicella;
ii. Member lacks immunity to varicella;
iii. VZIG is currently unavailable;
iv. Meets any of the following (any a - e):
a) Varicella vaccine is locally unavailable;
b) History of a severe allergic reaction (anaphylaxis) to the varicella vaccine;
c) Pregnancy;
d) Immunocompromised;
e) Newborn of mother who had varicella from 5 days before to 2 days after delivery;

d. Rubella post-exposure prophylaxis (i and ii):
i. Recent exposure to rubella;
ii. Member is pregnant;

Approval duration: one injection total* [*If extended stay (≥ 3 months) in area endemic for hepatitis A, repeat injection every 4-6 months]

D. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).
2. Compendial uses for IG are approved for the following indications per the CP.PHAR.57 Global Biopharm policy:
a. The following fetal/neonatal indications:
i. Thrombocytopenia;
ii. Alloimmune thrombocytopenia;
iii. Infectious disease prophylaxis;
b. Autoimmune hemolytic anemia;
c. Pure red cell aplasia in pediatric population;
d. Prophylaxis of bacterial infection in human immunodeficiency virus infection;
e. Refractory dermatomyositis and polymyositis;

f. Myasthenia gravis;
g. Relapsing-remitting multiple sclerosis;
h. Guillain-Barre syndrome;
i. Pemphigus vulgaris;
j. Stiff-man syndrome;
k. Toxic shock syndrome;
l. Transplant of kidney- pretransplant desensitization of highly sensitized patients

II. Continued Therapy

A. Intravenous Immune Globulin Formulations (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 6 months

B. Subcutaneous Immune Globulin Formulations (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 6 months

C. Intramuscular Immune Globulin Formulations (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: one injection total* [*If extended stay (≥ 3 months) in area endemic for hepatitis A, repeat injection every 4-6 months]

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
AMS: aseptic meningitis syndrome
CIDP: chronic inflammatory demyelinating polyneuropathy
CLL: chronic lymphocytic leukemia
CMV: cytomegalovirus
DIF: dual inactivation plus nanofiltration
IG: immune globulin

IgA: immune globulin A
IM: intramuscular
IMIG: immune globulin (IM route)
ITP: immune thrombocytopenic purpura
IV: intravenous
IVIG: immune globulin (IV route)
MMN: multifocal motor neuropathy
NF: nanofiltered
PI: primary [humoral] immunodeficiency
SC: subcutaneous
SCIG: immune globulin (SC route)
S/D: solvent/detergent treated
VZIG: varicella zoster immune globulin
CVID: common variable immunodeficiency

Appendix B: Immune Globulin Products by FDA Labeled Route and Indication

Brand Name	Route			Indication							
	IV	SC	IM	PI	ITP	CIPD	Kawasaki	MMN	CLL	CMV	Hep A*
Bivigam	IV			x†							
Carimune NF	IV			x†	x†						
Cuvitru		SC		x§							
Cytogam	IV									x†	
Flebogamma DIF (5%)	IV			x†							
Flebogamma DIF (10%)	IV			x†	x†						
GamaSTAN S/D			IM								x‡
Gammagard Liquid	IV	SC		x ^				x†			
Gammagard S/D	IV			x†	x†		x†		x†		
Gammaked	IV	SC		x^	x†	x†					
Gammaplex	IV			x†	x†						
Gamunex-C	IV	SC		x^	x†	x†					
Hizentra		SC		x§							
Hyqvia		SC		x§							
Octagam 5%	IV			x†							
Octagam 10%	IV				x†						
Privigen	IV			x†	x†						

*****GamaSTAN also is approved for measles, rubella and varicella post-exposure prophylaxis
Route: †IV only; ^IV or SC; §SC only; ‡IM only

IV. Dosage and Administration

Refer to full prescribing information for specific dosage instructions. Dosage must be individualized and is highly variable depending on the nature and severity of the disease and on the individual patient response. There is no absolute maximum dosage of immune globulin or hyaluronidase. See Appendix B for FDA labeled route and indication.

V. Product Availability

Drug	Availability

IV administration-Ready to use	
Bivigam (10%):	5, 10 gram single-use vials
Cytogam (5%)* *Contains a standardized amount of antibody to CMV (human)	2.5 gram single-use vial
Flebogamma DIF (5%)	0.5, 2.5, 5, 10, 20 gram single-use vials
Flebogamma DIF (10%)	5, 10, 20 gram single-use vials
Gammaplex (5%)	2.5, 5, 10, 20 gram single-use bottles
Octagam (5%)	1, 2.5, 5, 10, 25 gram single-use bottles
Octagam (10%)	2, 5, 10, 20 gram single-use bottles
Privigen (10%)	5, 10, 20, 40 gram single-use vials
IV administration-lyophilized powder for reconstitution	
Carimune NF	3, 6, 12 gram single-use vials
IV administration- Freeze dried for reconstitution	
Gammagard S/D	5%: 5 gram single-use bottle 10%: 10 gram single-use bottle
IV or SC administration-Ready to use	
Gammagard Liquid (10%)	1, 2.5, 5, 10, 20, 30 gram single-use bottles
Gammaked (10%)	1, 2.5, 5, 10, 20 gram single-use bottles
Gamunex-C (10%)	1, 2.5, 5, 10, 20, 40 gram single-use bottles
SC administration-Ready to use	
Cuvitru (20%)	1, 2, 4, 8 gram single-use vials
Hizentra (20%):	1, 2, 4, 10 gram single-use vials
Hyqvia (10%) IgG and 160 U/mL recombinant human hyaluronidase* *Hyaluronidase increases permeability of the local SC tissue for approximately 24 to 48 hours.	2.5g/200U, 5g/400U, 10g/800U, 20g/1600U, 30g/2400U dual-vial sets
IM administration-Ready to use	
GamaSTAN S/D (15-18%):	2 and 10 mL single-dose vials

VI. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added Bivigam for FDA-approved use for PID	08/13	08/13
Added Octagam 10% for ITP Updated Appendices Hematologist reviewed	08/14	09/14
Added compendial indications and criteria Added coding information Added clarity about Gamunex-C regarding formulary considerations Converted policy into new template and criteria into bullet points	08/15	09/15
Added Hyqvia and Cytogam. Removed failure of IVIG before SCIG.	01/16	03/16
Converted policy to new template. Removed renal/thrombosis dose adjustment criteria/appendices and replaced with discontinuation criteria if stated in PIs. For IVIG formulations, removed the following: "In transplants of the aforementioned organs (other than kidney) from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir;" For IMIG formulations, the following edits: Hepatitis A- Additional criteria applied to travel (i.e., in addition to departing within 2 weeks, age/immune status/chronic disease requirements); examples of exposure contacts broadened and illicit drug use is moved from a high risk example to a post-exposure contact example. Measles: Added indication of age <12 months. Varicella: Added indication of "newborn of mother who had varicella from 5 days before to 2 days after delivery." Measles and Varicella: added requirement that there be evidence of no immunity. Updated compendial indications per Micromedex (≥2b evidence level) and focused to uses expressed in	08/16	09/16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
present policy. Under the FDA indication section, footnotes are added for PI and ITP regarding age and acute/chronic ITP. Updated coding.		
Early revision to add Cuvitru approved in September, 2016.	11/16	12/16
Converted to new template. Initial: (IV) primary humoral immunodeficiency: clarified the strength of Octagam per PI; ITP: added Privigen to the list of IG products requested per PI; CIDP: removed Privigen from the list of IG products requested; (SC) primary humoral immunodeficiency, (IM) immunoglobulin: clarified extended stay (≥ 3 months) in the approval duration. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	08/17	09/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.