Clinical Policy: Immune Globulins

Reference Number: CP.PHAR.103
Effective Date: 08/12
Last Review Date: 08/16

Coding Implications
Revision Log

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

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for the immune globulin (IG) products: 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®

Policy/Criteria

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

I. Initial Approval Criteria

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

1. Request for intravenous IG 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, Privigen;
      ii. If request is not for Gamunex-C, member must have contraindication or intolerance to Gamunex-C;
   b. Immune 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%);
      ii. If request is not for Gamunex-C, member must have contraindication or intolerance 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), Privigen;
      ii. If request is not for Gamunex-C, member must have contraindication or intolerance 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;

2. Member has none of the following contraindications:
   a. Anaphylaxis or severe systemic reaction to IG or product components;
   b. Immune globulin A (IgA) deficient with antibodies against IgA AND a history of hypersensitivity (products contain trace amounts of IgA);
   c. If Privigen, hyperprolinemia (Privigen contains the stabilizer L-proline);
   d. If Octagam, acute hypersensitivity to corn (Octagam contains maltose, a disaccharide sugar derived from corn);
   e. If Gammaplex, hereditary intolerance to fructose; if an infant or neonate, contraindication includes if sucrose or fructose tolerance has not been established.

Approval duration: 6 months

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

1. Request for subcutaneous IG 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 intolerance 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;
3. Member has none of the following contraindications:
   a. Anaphylaxis or severe systemic reaction to IG or product components;
   b. IgA deficient with antibodies against IgA and a history of hypersensitivity (product contains trace amounts of IgA);
   c. If Hizentra, hyperprolinemia (type I or II) (Hizentra contains the stabilizer L-proline);
   d. If Hyqvia, systemic hypersensitivity to hyaluronidase, including recombinant human hyaluronidase which is present in Hyqvia.

Approval duration: 6 months

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

1. Request for intramuscular GamaSTAN S/D applies to 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. Varicella zoster immune globulin (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;

2. Member has none of the following contraindications:
a. Isolated IgA deficiency;
b. Severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.

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

D. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

1. 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 HIV (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 Approval

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;
3. Member has none of the following reasons to discontinue:
   a. Anaphylaxis or severe systemic reaction to IG or product components;
   b. IgA deficient with antibodies against IgA and a history of hypersensitivity (product contains trace amounts of IgA);
   c. If Privigen, hyperprolinemia (Privigen contains the stabilizer L-proline);
   d. If Octagam, acute hypersensitivity to corn (Octagam contains maltose, a disaccharide sugar derived from corn);
   e. If Gammaplex, hereditary intolerance to fructose; if an infant or neonate, contraindication includes if sucrose or fructose tolerance has not been established;
   f. If Bivigam, Flebogamma, Gammagard Liquid, Gammaked, Gammaplex, Gamunex-C, Octagam, or Privigen, deteriorating renal function in the presence of renal insufficiency and despite infusion rate adjustments.

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;
3. Member has none of the following reasons to discontinue:
   a. Anaphylaxis or severe systemic reaction to IG or product components;

b. IgA deficient with antibodies against IgA and a history of hypersensitivity (product contains trace amounts of IgA);
c. If Hizentra, hyperprolinemia (type I or II) (Hizentra contains the stabilizer L-proline);
d. If Hyqvia, systemic hypersensitivity to hyaluronidase including recombinant human hyaluronidase present in Hyqvia;
e. If Hyqvia, Hizentra, or Cuvitru, symptoms of aseptic meningitis syndrome (AMS).

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;
3. Member has none of the following contraindications:
   a. Isolated IgA deficiency;
   b. Severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.

Approval duration: one injection total*
*(*If extended stay 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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background
Description/Mechanism of Action:
IG products are derived from donated human plasma and used to treat a variety of disorders such as primary and secondary immune deficiency states and autoimmune and inflammatory disorders. While the exact mechanisms of action have not been fully elucidated for primary humoral immunodeficieny, ITP, CIDP, Kawasaki syndrome, CLL, or MMN, general mechanisms of action include anti-inflammatory and immunomodulatory effects, provision of neutralizing antibodies to microbial toxins, clearance/inhibition of immune complex deposits, regulatory T cell alteration, and pathogenic IgG clearance. Some IG products (e.g., Cytogam, GammaSTAN) are prepared from plasma of individuals with high titers of specific antibodies to certain pathogens and/or individuals who are hyperimmunized to specific antigens. These IG products are utilized as prophylaxis of infectious diseases, providing passive immunity in the setting of a known or expected exposure.

Formulations:
IgG (human)
IV administration
Ready to use
Bivigam (10%): 5, 10 gram single-use vials
Cytogam (5%)*: 2.5 gram single-use vial
**Contains a standardized amount of antibody to CMV (human)*

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
Lyophilized powder for reconstitution
Carimune NF: 3, 6, 12 gram single-use vials
Freeze dried for reconstitution
Gammgard S/D: (5%): 5 gram single-use bottle
Gammgard S/D: (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*: 2.5g/200U, 5g/400U, 10g/800U, 20g/1600U, 30g/2400U dual-vial sets
**Hyaluronidase increases permeability of the local subcutaneous tissue for approximately 24 to 48 hours.*
IM administration
Ready to use
GamaSTAN S/D (15-18%): 2 and 10 mL single-dose vials

FDA Approved Indications:
IG products identified in this policy are approved for the following uses *(see Table One below for individual products by route and indication):*

- IVIG formulations:
  - Primary humoral immunodeficiency: for replacement therapy.*
  - ITP (acute/chronic): Treatment to raise platelet counts, including to prevent bleeding or allow surgery.**
  - 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].
  - MMN: Maintenance therapy to improve muscle strength and disability in adult patients.
  - B-cell CLL: Prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell CLL.
  - 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.

- SCIG formulations:
  - Primary humoral immunodeficiency: for replacement therapy.
- 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.*

Table One: 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†		

Brand Name	Route			Indication							
	IV	SC	IM	PI	ITP	CIPD	Kawasaki	MMN	CLL	CMV	Hep A*
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

Appendices

Appendix A: Abbreviation Key

AMS: aseptic meningitis syndrome
CIDP: chronic inflammatory demyelinating polyneuropathy
CLL: chronic lymphocytic leukemia
CMV: cytomegalovirus
DIF: dual inactivation plus nanofiltration
HIV: human immunodeficiency virus
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
PRCA: pure red cell aplasia
SC: subcutaneous
SCIG: immune globulin (SC route)
S/D: solvent/detergent treated
VZIG: varicella zoster immune globulin

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
90281	Immune globulin (Ig), human, for intramuscular use
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each
90399	Unlisted immune globulin
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour

CPT® Codes	Description
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

HCPCS Codes	Description
J0850	Injection, cytomegalovirus immune globulin intravenous (human), per vial
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin (gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1559	Injection, immune globulin (hizentra), 100 mg
J1561	Injection, immune globulin (Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562	Injection, immune globulin (Vivaglobin), 100 mg
J1566	Injection, immune globulin, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard Liquid), non-lyophilized (e.g., liquid), 500 mg
J1572	Injection, immune globulin (flebogamma/flebogamma DIF) intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg

ICD-10-CM Diagnosis Codes that Support Medical Necessity

ICD-10-CM Code	Description
A48.3	Toxic shock syndrome
B15.9	Hepatitis A without hepatic coma
B20	Human immunodeficiency virus (HIV) disease
B25.8	Other cytomegaloviral diseases
B25.9	Cytomegaloviral disease, unspecified
B34.3	Parvovirus infection, unspecified
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D59.0	Drug-induced autoimmune hemolytic anemia
D59.1	Other autoimmune hemolytic anemias

ICD-10-CM Code	Description
D61.01	Constitutional (pure) red blood cell aplasia (primary pure red cell aplasia)
D69.3	Immune thrombocytopenic Purpura
D69.41	Evans syndrome
D69.49	Thrombocytopenia Purpura
D69.51	Posttransfusion Purpura
D69.59	Other secondary thrombocytopenia
D80.0	Hereditary hypogammaglobulinemia (X-linked, congenital)
D80.1	Nonfamilial hypogammaglobulinemia
D80.5	Immunodeficiency with increased immunoglobulin M (IgM)
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency (SCID) with reticular dysgenesis
D81.1	Severe combined immunodeficiency (SCID) with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency (SID) with low or normal B-cell numbers
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiencies, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
D82.9	Immunodeficiency associated with other specified major defects
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
G25.82	Stiff-man syndrome
G35	Multiple sclerosis
G61.0	Guillain-Barre syndrome
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.89	Other inflammatory polyneuropathies
G61.9	Inflammatory polyneuropathy, unspecified
G70.01	Myasthenia gravis with (acute) exacerbation
G73.3	Myasthenic syndromes in other diseases classified elsewhere
L10.0	Pemphigus vulgaris
L10.1	Pemphigus vegetans
L10.2	Pemphigus follaceous

ICD-10-CM Code	Description
L10.4	Pemphigus erythematosus
L10.9	Pemphigus, unspecified
L12.0	Bullous pemphigoid
L12.1	Cicatricial pemphigoid
L12.30	Acquired epidermolysis bullosa, unspecified
L12.31	Epidermolysis bullosa due to drug
L12.35	Other acquired epidermolysis bullosa
L12.8	Other pemphigoid
L13.8	Other specified bullous disorders
L51.1	Stevens-Johnson syndrome
L51.2	Toxic epidermal necrolysis
L51.3	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
M30.3	Mucocutaneous lymph node syndrome (Kawasaki)
M33.00	Juvenile dermatopolymyositis, organ involvement unspecified
M33.01	Juvenile dermatopolymyositis with respiratory involvement
M33.02	Juvenile dermatopolymyositis with myopathy
M33.09	Juvenile dermatopolymyositis with other organ involvement
M33.10	Other dermatopolymyositis, organ involvement unspecified
M33.11	Other dermatopolymyositis with respiratory involvement
M33.12	Other dermatopolymyositis with myopathy
M33.19	Other dermatopolymyositis with other organ involvement
M33.20	Polymyositis, organ involvement unspecified
M33.21	Polymyositis with respiratory involvement
M33.22	Polymyositis with myopathy
M33.29	Polymyositis with other organ involvement
M33.90	Dermatopolymyositis, unspecified, organ involvement unspecified
M33.91	Dermatopolymyositis, unspecified with respiratory involvement
M33.92	Dermatopolymyositis, unspecified with myopathy
M33.99	Dermatopolymyositis, unspecified with other organ involvement
P55.0	Rh isoimmunization of newborn (hemolytic disease of newborn)
P55.1	ABO isoimmunization of newborn (hemolytic disease of newborn)
P61.0	Transient neonatal thrombocytopenia
T86.00	Unspecified complication of bone marrow transplant
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.09	Other complications of bone marrow transplant
T86.10	Unspecified complication of kidney transplant
T86.11	kidney transplant rejection
T86.12	kidney transplant failure
T86.20	Unspecified complication of heart transplant
T86.21	Heart transplant rejection
T86.22	Heart transplant failure

ICD-10-CM Code	Description
T86.40	Unspecified complication of liver transplant
T86.41	Liver transplant rejection
T86.42	Liver transplant failure
T86.810	Lung transplant rejection
T86.811	Lung transplant failure
Z20.4	Contact with and (suspected) exposure to rubellayes
Z20.820	Contact with and (suspected) exposure to varicella
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases (eg. measles, hepatitis A)
Z79.899*	Other long term (current) drug therapy [use for prophylactic immunotherapy for high-risk, preterm, low-weight neonates]
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.81	Bone marrow transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status

*For prevention of infection for high-risk, preterm, low-weight neonates, the claim should contain 2 diagnosis codes: the prophylaxis code Z79.899 plus the applicable low-birth-weight code from within the P07.00-P07.18 range.

Reviews, Revisions, and Approvals	Date	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.	08/16	09/16

Reviews, Revisions, and Approvals	Date	Approval Date
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 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

References

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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.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.