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RX.PA.017.MPC Intravenous Immune Globulin (IVIG), Subcutaneous Immune Globulin (SCIG) & Intramuscular Immune Globulin (IMIG)

The purpose of this policy is to define the prior authorization process for all commercially-available, formulary IVIG and SCIG products.

DEFINITIONS

INCAT (Inflammatory Neuropathy Cause and Treatment Scale) – is used to assess functional disability of both upper and lower extremities in chronic inflammatory demyelinating polyradiculoneuropathy (CIDP).

Grade	**Arm Disability**
0	No upper limb problems
1	Symptoms, in one or both arms, not affecting the ability to perform any of the following functions: doing all zips and buttons; washing or brushing hair; using a knife and fork together; an handling small coins
2	Symptoms, in one arm or both arms, affecting but not preventing any of the above-mentioned functions
3	Symptoms, in one arm or both arms, preventing one or two of the above-mentioned functions
4	Symptoms, in one arm or both arms, preventing three or all of the functions listed, but some purposeful movements still possible
5	Inability to use either arm for any purposeful movement
Grade	**Leg Disability**
0	Walking not affected
1	Walking affected, but walks independently outdoors
2	Usually uses unilateral support (stick, single crutch, one arm) to walk outdoors
3	Usually uses bilateral support (stick, crutches, frame, two arms) to walk outdoors
4	Usually uses wheelchair to travel outdoors, but able to stand and walk a few steps with help
5	Restricted to wheelchair, unable to stand and walk a few steps with help

Inflammatory Rasch-built Overall Disability Scale (I-RODS) – intended to specifically assess activity and social participation limitations in patients with inflammatory neuropathies

Overall Disability Sum Score (ODSS) / Overall Neuropathy Limitations Scale (ONLS) – focuses on upper and lower limb functions and consists of a checklist for interviewing patients. The ODSS was the first scale designed to assess the limitations of patients with immune-mediated peripheral neuropathies. To reduce a possible ceiling effect, the ODSS was modified to include climbing stairs and running. The new measure is called the ONLS.

Grade	Arm Disability
0	Normal
1	Minor symptoms in one or both arms but not affecting any of the functions listed
2	Disability in one or both arms affecting but not preventing any of the functions listed
3	Disability in one or both arms preventing at least one but not all functions listed
4	Disability in both arms preventing all functions listed but purposeful movement still possible
5	Disability in both arms preventing all purposeful movements

Grade	Leg Disability
0	Walking/climbing stairs/running not affected
1	Walking/climbing stairs/running is affected, but gait does not look abnormal
2	Walks independently but gait looks abnormal
3	Requires unilateral support to walk 10 metres (stick, single crutch, one arm)
4	Requires bilateral support to walk 10 metres (sticks, crutches, crutch and arm, frame)
5	Requires wheelchair to travel 10 metres but able to stand and walk 1 metre with the help of one person
6	Restricted to wheelchair, unable to stand and walk 1 metre with the help of one person, but able to make some purposeful leg movements
7	Restricted to wheelchair or bed most of the day, unable to make any purposeful movements of the legs

Refractory Myasthenia Gravis Disease- unchanged or worse disease after corticosteroids and at least 2 other immunosuppressants, used in adequate doses for an adequate duration, with persistent symptoms or side effects that limit functioning, as defined by patient and physician.

The drugs, intravenous immune globulin (IVIG) and subcutaneous immune globulin (SCIG), are subject to the prior authorization process.

A. PROCEDURE

IVIG and SCIG are used to increase circulating levels of gamma globulin in certain immunoglobulin deficiency states and in treatment of a limited number of specified diseases.

FDA Approved Products and Indications (IVIG, SCIG, IMIG)

Product Name	Route of Administration	PID	ITP	CLL	CIDP	KD	MMN	DM	Hepatitis A	Measles	Varicella
Asceniv	IV	X									
Bivigam	IV	X									
Carimune NF	IV	X	X								
Cutaquig	SC	X									
Cuvitru	SC	X									
Flebogamma DIF	IV	X									
Gamastan S/D	IM								X	X	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			X						
Hyqvia	SC	X									
Octagam	IV	X	X					X			
Panzyga	IV	X	X		X						
Privigen	IV	X	X		X						
Xembify	SC	X									

FDA approved indications for specific Ig products:

- Primary Immunodeficiency Diseases (PID) [includes, but are not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies]
- Idiopathic thrombocytopenic purpura (ITP)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Kawasaki Disease (KD)
- Multifocal Motor Neuropath (MMN)
- Dermatomyositis (DM)

- IVIG products will not be approved for subcutaneous use unless FDA approved for that route of administration
- Requests for FDA approved indications should utilize the preferred associated specific Ig products listed in the table above

NOTE: Eviti reviews prior authorization requests for all oncology related indications for Ig products.
Must meet all of the criteria listed below:

FDA Approved Indications
1. For Primary Immunodeficiency

- Syndromes may include:
  - Common Variable Immunodeficiency (Hypogammaglobulinemia)
  - Congenital Agammaglobulinemia
  - Bruton's or X-linked Agammaglobulinemia
  - Severe Combined Immunodeficiency (SCID)
  - X-linked Hyper-IgM Syndrome
  - Wiskott-Aldrich Syndrome
  - Hypergammaglobulinemia Types
- Must be prescribed by or in consultation with an immunologist or hematologist
- Must have deficient antibody production, as evidenced through a documented IgG level ≤500mg/dL*
  - Requests with IgG levels >500mg/dL require chart documentation that provides clinical rationale for the use of IVIG or SCIG (**NOTE:** Several primary immunodeficiencies do have normal levels of IgG with documented specific antibody deficiency)
  - *Note: Members under the age of 1 normally possess lower IgG levels
- Must have history of at least 1 bacterial infection directly attributable to this deficiency
- Approve for 1 year initially
- Approval will be based off of FDA approved indication with specific associated IG products. Please refer to the table above.

For Primary Immunodeficiency

- Syndromes may include:
  - Common Variable Immunodeficiency (Hypogammaglobulinemia)

2. For Idiopathic or Immune Thrombocytopenic Purpura (ITP)

(Platelet counts expressed per mm3)

- Must be prescribed by a hematologist or oncologist
- For children with ITP:
  - Must have ONE of the following:
    - Active bleeding AND platelet count <30,000
    - Upcoming invasive surgery AND either platelet level below threshold designated for procedure (threshold must be provided with request) OR blood loss is expected
    - Non-life-threatening mucosal bleeding and/or diminished quality of life AND documented previous inadequate response or intolerance to corticosteroids
- For adults with ITP:
  - Must have ONE of the following:
    - Active bleeding AND platelet count <30,000
    - Upcoming invasive surgery AND platelet level below threshold designated for procedure (threshold must be provided with request)
    - Platelet count <30,000 AND documented previous inadequate response or intolerance to corticosteroids
- For pregnant women with ITP
  - Must be pregnant and have ONE of the following:
    - Platelet count <50,000
    - Upcoming invasive surgery/procedure
    - History of splenectomy
    - Previously delivered infants with autoimmune thrombocytopenia
- Approve for 1 month
- Approval will be based off of FDA approved indication with specific associated IG products. Please refer to the table above.
- **DOSING NOTE:** Clinical guidelines recommend up to 1,000mg/kg/dose as a 1-time dose; dosage may be repeated if necessary.

3. For Kawasaki Disease

- Prescribed by or in consultation with a pediatric cardiologist or infectious disease physician
- Must be receiving aspirin concomitantly
- Must be requesting treatment within the first 10 days of illness
  - If greater than 10 days after illness onset, persistent signs of inflammation (e.g., persistent fever without explanation, elevated ESR or CRP, coronary artery aneurysms)
- Approve for 1 dose
- Approval will be based off of FDA approved indication with specific associated IG products. Please refer to the table above.
- **DOSING NOTE:** Clinical guidelines recommend 2 grams/kg

4. For HIV (Human Immunodeficiency Virus) in pediatric patients

- Must be prescribed by an immunologist or infectious disease specialist
- Must be <13 years old
- Must have CD4 count ≥200/mm3

- Must have ONE of the following
    - Recurrent (2 or more) serious bacterial infections such as bacteremia, meningitis, or pneumonia during a 1-year period despite administration of highly active antiretroviral therapy (HAART) and prophylactic sulfamethoxazole/trimethoprim (TMP-SMZ) or other antimicrobials
    - Hypogammaglobulinemia with an IgG <400mg/dL
    - Absence of detectable antibodies to common antigens, (measles, pneumococcal, and/or haemophilus influenzae Type B)
    - Bronchiectasis not optimally responsive to antibiotics and pulmonary therapy
    - A need for passive immunization for measles if Intramuscular Immune Globulin (IMIG) is contraindicated. IM injection contraindicated with severe thrombocytopenia or any coagulation disorder
- Approve for 1 year
- Approval will be based off of FDA approved indication with specific associated IG products. Please refer to the table above.
- **DOSING NOTE:** Clinical guidelines recommend 400mg/kg every 2-4 weeks

5. <u>For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)</u>

- Must be prescribed by a neurologist
- Must have a diagnosis of CIDP
- Must provide documentation of electrodiagnostic testing (an EMG report)
- Must have moderate-to-severe functional disability
- Must provide a baseline disability score (using a validated disability scale, such as I-RODs, ODSS, ONLS, or INCAT)
- Approve for 3 months
- Approval will be based off of FDA approved indication with specific associated IG products. Please refer to the table above.

6. For Multifocal Motor Neuropathy

- Must be prescribed by a neurologist
- Must provide chart note documentation supporting a clinical examination of the member and BOTH of the following:
    - Progressive, asymmetric limb weakness over a course of at least 1 month

    - No objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs
- Must provide documentation of electrodiagnostic testing (an EMG report)
- Approve for 2 months
- Approval will be based off of FDA approved indication with specific associated IG products. Please refer to the table above.
- **DOSING NOTE:** Clinical guidelines recommend up to 2g/kg given over 2-5 days

7. For Dermatomyositis and Polymyositis (including juvenile)

- Must have dermatomyositis and polymyositis confirmed by biopsy
- Prescribed by or in consultation with a neurologist or rheumatologist
- Must have tried and failed or have a contraindication to both of the following:
    - Corticosteroids for 3 months
    - Concomitant adjuvant therapy for at least 3 months (azathioprine, methotrexate, cyclosporine)
- Approve for 2 months for either diagnosis
- Approval will be based off of FDA approved indication with specific associated IG products. Please refer to the table above.

8. GamaSTAN S/D

- Prophylaxis of Hepatitis A:
    - Must be prescribed by an infectious disease specialist
    - Must not present clinical manifestations of hepatitis A
    - Must not have been exposed to hepatitis A for more than 2 weeks

- Prophylaxis of Measles:
    - Must be prescribed by an infectious disease specialist
    - Must not have been exposed to measles for 6 days or more
    - Must not be given concurrently with the measles vaccine

- Prophylaxis of Varicella:
    - Must be prescribed by an infectious disease specialist
    - Must have been exposed to varicella within the last 10 days

Off-label Uses

1. <u>For Guillain-Barre Syndrome</u>

- Must start IVIG within 4 weeks of onset of neuropathic symptoms
- Must be unable to walk independently
- Prescribed by or in consultation with a neurologist
- Approve for 1 month
- May approve 1 additional month

2. <u>For Systemic Lupus Erythematosus (SLE)</u>

- Must have severe active SLE
- Must have tried and failed or have contraindications to ALL of the following:
    - Corticosteroids

  - Antimalarials
  - 1 additional immunosuppressant (azathioprine, cyclophosphamide, cyclosporine, methotrexate)
- Approve for 3 months

3. <u>For Multiple Sclerosis (MS)</u>

- Must be prescribed by a neurologist
- For acute exacerbations of MS:
  - Must have a trial and failure or have contraindications to corticosteroids and plasma exchange
  - Approve for 1 month
  - Additional authorizations for treatment are made on a case-by-case basis, are subject to the above criteria, and require chart documentation describing previous response to treatment and clinical rationale for re-treatment if IVIG did not provide a sufficient response.
- For chronic maintenance treatment of MS:
  - Must have relapsing, remitting type of MS
  - Must have a trial and failure (duration of at least 3 months) or have contraindications to ALL of the following:
    - At least one interferon [interferon beta-1a (Avonex®, Rebif®) or interferon beta-1b (Betaseron®, Extavia®)]
    - Glatiramer (Copaxone®)
    - Fingolimod (Gilenya®)
  - No previous trials are required if:
    - Member is pregnant
    - Member is immunosuppressed or is having recurrent infections
  - Approve for 6 months

4. <u>For Autoimmune Mucocutaneous Blistering Disease (AMBD)</u>

- Must have one of the following supported by biopsy:
  - Pemphigus vulgaris
  - Pemphigus foliaceus
  - Bullous pemphigoid
  - Mucous membrane pemphigoid (a.k.a., cicatricial pemphigoid), OR
  - Epidermolysis bullosa acquisita
- Must have a trial and failure or have contraindications to corticosteroids and immunosuppressive agents
- EXCEPTION: In rapidly progressive, extensive, or debilitating cases IVIG may be approved along with corticosteroids or immunosuppressive agents
- Approve for 4 months

5. <u>For Myasthenia Gravis Syndrome</u>

- Must have a diagnosis of Myasthenia Gravis
- Must be prescribed by a neurologist
- For acute use:
  - Chart documentation of acute exacerbation and impaired function is required (e.g. respiratory insufficiency, inability to swallow)
  - Approve for 1 month
- For temporary use as a bridge to immunotherapy:
  - Must have a history of myasthenia gravis exacerbation
  - Must be recently started (within 3 months) on immunosuppressant therapy (e.g. azathioprine, mycophenolate, cyclosporine, or tacrolimus)

    - Chart documentation of use as bridge therapy is required
    - Approve for 6 months
- For stabilization prior to surgery:
    - Must have a history of myasthenia gravis with current or previous difficulty with swallowing, speech, or respiratory involvement (e.g. shortness of breath or reduce force vital capacity on pre-op pulmonary function test). Chart documentation of symptoms is required.
    - IVIG infusion must be scheduled within 14 days of anticipated surgery date
    - Approve for 1 month
- For chronic use in refractory disease:
    - Must have an adequate trial with inadequate response, significant side effects/toxicity, or have a contraindication to both of the following:
        - Cholinesterase inhibitors- pyridostigmine or neostigmine
        - Corticosteroids
    - Must have an adequate trial of at least 3 months each with inadequate response, significant side effects/toxicity, or have a contraindication to TWO of the following:
        - Azathioprine
        - Mycophenolate mofetil
        - Cyclosporine
        - Tacrolimus
    - Approve for 6 months

6. <u>For Parvovirus B19 Infection</u>

- Must have documentation (e.g. Polymerase Chain Reaction test result) confirming presence of HPV-B19 infection
- Must have severe anemia defined as hemoglobin level <8ng/dL
- Must have low reticulocyte count defined as <8x109/L
- Must have history of immunodeficiency due to suppressive medications or HIV
- Approve for 1 month
- **DOSING NOTE:** Clinical guidelines recommend 400-500mg for 5 days

7. <u>For Renal and/or Pancreatic Transplant Desensitization in Combination with Rituxan</u>

- Must be prescribed by a transplant specialist
- Must be age 18 or older
- Must be awaiting kidney and/or pancreas transplant requiring desensitization as defined by the following criteria:
    - For deceased donor transplants:
        - Panel reactive antibody (PRA) level >30% **OR**
        - PRA <30% with previous kidney and/or pancreas transplant
    - For living donor transplants:
        - Positive crossmatch **OR**
        - Positive donor-specific antibody using Luminex® assay
- Approve for 1 course of treatment (2 doses)

8. <u>For Renal Transplant Desensitization</u>

- Must be prescribed by a transplant specialist
- Must be awaiting kidney transplant (either from a living or deceased donor) and requiring desensitization
- Approve for 4 months

9. For Renal Post-Transplant Rejection

- Must have received a renal transplant from a living donor with post-transplant rejection
- Approve for 1 month

10. For Allogenic or Hematopoietic Stem Cell Transplantation (HSCT) (or Bone Marrow Transplant)

- Must have severe hypogammaglobulinemia (IgG <400 mg/dL)
- Must have history of recurrent infections
- Approve for 6 months

11. For Autoimmune Hemolytic Anemia

- Must have warm-type diagnosis
- Must have a trial and failure or have contraindications to corticosteroids
- Approve for 1 month

12. For Stiff-Person Syndrome

- Must have a diagnosis of Stiff-Person Syndrome confirmed by electromyography (EMG) or elevated levels of glutamic acid decarboxylase (GAD)
- Must be prescribed by a neurologist
- Must have an adequate trial with inadequate responses, significant side effects/toxicity, or have contraindications to THREE of the following:
    - Corticosteroids
    - Antiepileptics
    - Benzodiazepines
    - Muscle relaxants
    - Gabapentin
- Approve for 4 months

13. Steven's Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN)

- Initial approval is 1 month (2 doses)
- **DOSING NOTE:** Package insert/clinical guidelines recommend 1 g/kg/day in divided doses for 3-4 days

14. CAR-T Therapy-Related Toxicity

- Must be prescribed by a hematologist, oncologist, or infectious disease specialist
- Must have Hypogammaglobinemia (IgG level <400mg/dL)
- Must have documentation of serious or recurrent infections (particularly bacterial)
- Initial approval is 1 year
- **DOSING NOTE:** Clinical guidelines recommend 400-500mg/kg monthly

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. IV and subcutaneous immune globulin products will be considered investigational or experimental for any other use and coverage may be provided if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, DrugDex, Lexi-Drug, etc…) or at least two published peer-reviewed randomized controlled trials for the treatment of the diagnosis(es) for which it is prescribed. Abstracts (including meeting abstracts) are excluded from review consideration. These requests will be reviewed on a case by case basis to determine medical necessity.

Reauthorization Criteria:
All prior authorization renewals are reviewed to determine the Medical Necessity for continuation of therapy. Authorization may be extended based upon:

- MPC Renewal:
  - Chart documentation from the provider that the member's condition has stabilized or improved based upon the prescriber's assessment while on therapy and clinical rationale for re-treatment
  - FDA approved indications should use the specific associated IG products. Please refer to the table above.
  - No reauthorizations allowed for GamaSTAN S/D
- Non-MPC Renewal:
  - Members who have previously been taking Ig and are requesting a non-MPC renewal should be considered under Initial Authorization Criteria.
  - Provider has a documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment.

Additional Reauthorization Criteria:

1. **Primary Immunodeficiency**

- Reauthorization approval: 1 year
- Must submit documentation from the prescriber of an updated IgG level (within 60 days of the renewal request)

2. **Idiopathic or Immune Thrombocytopenic Purpura (ITP)**

- Reauthorizations are granted on a case-by-case basis and are subject to the initial criteria
- Must provide documented initial response to IVIG therapy
- Documentation of continued thrombocytopenia <20,000 or < 30,000 and clinically significant bleeding
- **DOSING NOTE:** Clinical guidelines recommend up to 1,000mg/kg/dose
- Reauthorization approval: 3 months

3. **Kawasaki Disease**

- First reauthorization is granted (approval of only 1 dose) based upon documentation showing the member failed to respond to therapy
- Additional authorizations for treatment are made on a case-by-case basis and are subject to the initial criteria
- Provider must submit documentation describing treatment response and clinical rationale for retreatment
- **DOSING NOTE:** Clinical guidelines recommend 2 grams/kg
- Reauthorization approval: 1 dose

4. **HIV (Human Immunodeficiency Virus) in pediatric patients**

- Additional authorizations for treatment are made on a case-by-case basis and are subject to the initial criteria
- **DOSING NOTE:** Clinical guidelines recommend 400mg/kg every 2-4 weeks
- Reauthorization approval: 1 year

5. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Reauthorizations are granted based upon documentation from the prescriber indicating the member's condition has improved as a result of treatment as evidenced by improvement or stability in the member's baseline disability score (using a validated disability scale, such as I-RODS, ODSS, ONLS, or INCAT).
- Reauthorization approval: 1 year

6. Multifocal Motor Neuropathy

- **DOSING NOTE:** Clinical guidelines recommend up to 2g/kg given over 2-5 days
- Reauthorization approval: 1 year

7. Dermatomyositis and Polymyositis (including juvenile)

- Reauthorization approval for Dermatomyositis: 1 year
- Reauthorization approval for Polymyositis: 2 months

8. Guillain-Barre Syndrome

- Additional authorizations for treatment are made on a case-by-case basis and are subject to the initial criteria
- Reauthorization approval: 1 month

9. Systemic Lupus Erythematosus (SLE)

- Reauthorization approval: 1 year

10. Multiple Sclerosis (MS)

- Additional authorizations for treatment are made on a case-by-case basis and are subject to the initial criteria
- **For acute exacerbations of MS:**
  - Reauthorization approval: 1 month
- **For chronic maintenance treatment of MS:**
  - Reauthorization approval: 6 months

11. Autoimmune Mucocutaneous Blistering Disease (AMBD)

- Additional authorizations for treatment are made on a case-by-case basis and are subject to the initial criteria
- Reauthorization approval: 4 months

12. Myasthenia Gravis Syndrome

- Reauthorizations are granted on a case by case basis and are subject to the initial criteria
- **For acute use:**
  - Reauthorization approval: 1 month
- **For temporary use as a bridge to immunotherapy:**
  - Reauthorization approval: 6 months
- **For stabilization prior to surgery:**

  - Reauthorization approval: 1 month
  - Must submit documentation on clinical rationale for reauthorization
- **For chronic use in refractory disease:**
  - Must have chart documentation describing previous response to treatment, including improvement in symptoms that limit daily function
  - Reauthorization approval: 6 months

13. Parvovirus B19 Infection

- Additional authorizations for treatment made on a case-by-case basis and are subject to the initial criteria
- **DOSING NOTE:** Clinical guidelines recommend 400-500mg for 5 days
- **Reauthorization approval:** 1 month
- **Maximum of 1 reauthorization per 365 days**

14. Renal and/or Pancreatic Transplant Desensitization in Combination with Rituxan

- Additional authorizations for treatment are subject to the initial criteria and are not granted until 6 months have passed since the initial treatment.
- Reauthorization approval: 1 course of treatment (2 doses)

15. Renal Transplant Desensitization

- Additional authorizations are not granted until 12 months have passed since the initial treatment.
- Reauthorization approval: 4 months

16. Renal Post-Transplant Rejection

- Reauthorization approval: 1 month

17. Allogenic or Hematopoietic Stem Cell Transplantation (HSCT) (or Bone Marrow Transplant)

- Additional authorizations for treatment are made on a case-by-case basis and are subject to the initial criteria
- Reauthorization approval: 6 months

18. Autoimmune Hemolytic Anemia

- Additional authorizations for treatment are made on a case-by-case basis and are subject to the initial criteria
- Reauthorization approval: 1 month

19. Stiff-Person Syndrome

- Reauthorization for an additional 2 months of treatment may be made on a case-by-case basis and is subject to the initial criteria
- Reauthorization approval: 2 months
- Continued use beyond 6 months of therapy is not authorized.

20. Steven's Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN)

- Reauthorizations are granted on a case-by-case basis and are subject to the initial criteria
- **DOSING NOTE:** Package insert/clinical guidelines recommend 1 g/kg/day in divided doses for 3-4 days
- Documentation of a new episode
- Reauthorization approval: 1 month (2 doses)

21. CAR-T Therapy-Related Toxicity

- **DOSING NOTE:** Clinical guidelines recommend 400-500mg/kg monthly
- Reauthorization approval: 1 year

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Case-by-Case bases (see criteria above)
Reauthorization	Case-by-Case bases (see criteria above)

If the established criteria are not met, the request is referred to a Medical Director for review.

HCPCS Code(s):

Code	Description
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1556	Injection, immune globulin (Cuvitru), 100 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1560	Injection, gamma globulin, intramuscular, over 10 cc
J1561	Injection, immune globulin, (Gamunex/Gamunex-C/Gammaked), nonlyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1551	Injection, immune globulin (cutaquig), 100 mg
J1558	Injection, immune globulin (xembify), 100 mg
J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg (Panzyga)
J1460	Injection, gamma globulin, intramuscular, 1 cc
J1560	Injection, gamma globulin, intramuscular, over 10 cc

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Selected Revision: Update to reauthorization criteria based on case by case indications	*03/2023*
Annual Review	*02/2023*
Selected Revision: Update to FDA approved products per indication *Addition of reauthorization criteria* *Addition of FDA approved indications for GamaSTAN S/D*	*01/2023*
Update to off-label restrictions	*04/2022*
Annual review	*02/2022*
Addition of new indications for SJS/TEN and Car-T Therapy-Related Toxicity criteria update for: AMBD, CIDP, Guillain Barre, ITP, MN, Myasthenia Gravis Syndrome	*02/2022*

Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*