STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUNE GLOBULIN	BIVIGAM, CARIMUNE NF NANOFILTERED, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA	04202 41798 41995		GPI-10 (1910002020) (1910002010) (1910002000) (1910002030)	
IMMUNE GLOB, GAM CAPRYLATE	GAMUNEX-C, GAMMAKED	25631		GPI-10 (1910002030)	
IMMUNE GLOBULIN / MALTOSE	OCTAGAM	33220		GPI-10 (1910002010)	
IGG/HYALURONIDASE, RECOMBINANT	HYQVIA	41391		GPI-10 (1999000235)	
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU	41796		GPI-10 (1910002020)	
IMMUN GLOB G(IGG)-IFAS/GLYCINE	PANZYGA	45354		GPI-10 (1910002060)	
IMMUN GLOB G(IGG)-HIPP/MALTOSE	CUTAQUIG	45734		GPI-10 (1910002057)	
IMMUNE GLOBULIN (HUMAN)-KLHW	XEMBIFY	45891		GPI-10 (1910002064)	
IMMUNE GLOBULIN (HUMAN)-SLRA	ASCENIV	46208		GPI-10 (1910002080)	

This drug must be reviewed by a pharmacist.

GUIDELINES FOR USE

1. Is the request for use as a subcutaneous injection?

   If yes, continue to #2.
   If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

2. Is the request for Hizentra and will be used for **ONE** of the following diagnoses?
   - Primary immunodeficiency disease (PID)
   - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

   If yes, **approve for 12 months by GPID or NDC (Medi-Span).**
   If no, continue to #3.

3. Is the request for Gammagard Liquid, Cuvitru, Gamunex-C, Gammaked, Hyqvia, Cutaquig, or Xembify? (**NOTE:** Gammagard Liquid, Gamunex-C and Gammaked may be given via SC or IV route.)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a primary immunodeficiency disease (PID)?

   If yes, **approve the requested agent for 12 months as follows:**
   - **Gammagard Liquid, Gamunex-C or Gammaked: Approve by NDC (FDB or Medi-Span).**
   - **Cuvitru: Approve by HICL or NDC (Medi-Span).**
   - **Hyqvia, Cutaquig, or Xembify: Approve by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for use as an intravenous (IV) injection or intramuscular (IM) injection? (**NOTE**: Bivigam, Carimune NF Nanofiltered, Flebogamma, Gamastand S-D, Gammagard S-D, Gammaplex, Privigen, Octagam, Panzyga, and Asceniv are not self-administered (NSA) agents and may not be covered by some plans)

   If yes, continue to #6.
   If no, guideline does not apply.

6. Is the request for Cuvitru, Hizentra, Hyqvia or Xembify? (**NOTE:** Cuvitru, Hizentra, Hyqvia and Xembify are indicated only for SC route)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #7.

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

7. Is the request for Asceniv and meet **ALL** of the following criteria?
   - The request is for primary immunodeficiency disease (PID)
   - The patient is 12 years of age or older
   - The patient has tried any other **TWO** immunoglobulin products (e.g., Panzyga, Bivigam, Flebogamma DIF, Gammaplex, Octagam, Privigen)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Is the request for Gamastan S/D? (**NOTE**: Gamastan S/D is indicated for intramuscular use only)

   If yes, continue to #9.
   If no, continue to #10.

9. Is Gamastan S/D being used for hepatitis A, measles, varicella, or rubella prophylaxis, or passive immunization?

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have **ONE** of the following diagnoses?
    - Primary Immunodeficiency Disease (PID)
    - Idiopathic Thrombocytopenic Purpura (ITP)
    - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
    - Multifocal Motor Neuropathy (MMN)
    - Kawasaki Syndrome
    - B-cell Chronic Lymphocytic Leukemia (CLL) with Hypogammaglobulinemia, Autoimmune Hemolytic Anemia (AIHA), Immune Thrombocytopenic Purpura (ITP), or pure Red Blood Cell Aplasia (PRCA)
    - Guillain-Barre Syndrome (GBS)
    - Myasthenia Gravis
    - Autoimmune Graves' Ophthalmopathy
    - Cytomegalovirus-induced Pneumonitis related to a solid organ transplant
    - Prevention of bacterial infection in an HIV-infected child
    - Reduction of secondary infections in pediatric HIV infections
    - Dermatomyositis or polymyositis
    - Autoimmune uveitis (Birdshot retinochoroidopathy)
    - Lambert-Eaton myasthenic syndrome
    - IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
    - Stiff-man syndrome
    - Neonatal sepsis
    - Rotaviral enterocolitis
    - Toxic shock syndrome
    - Enteroviral meningoencephalitis
    - Toxic Epidermal Necrolysis or Stevens-Johnson syndrome
    - Autoimmune Mucocutaneous Blistering Disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

    If yes, **approve the requested agent for 12 months as follows:**
    - **Gammagard Liquid, Gamunex-C, Gammaked, Bivigam, Flebogamma DIF, Gammaplex, or Privigen: Approve by NDC (FDB or Medi-Span).**
    - **Carimune NF Nanofiltered: Approve by GPID or GPI-14.**
    - **Gammagard S-D: Approve by NDC (FDB) or GPI-14.**
    - **Octagam: Approve by HICL or NDC (Medi-Span).**
    - **Panzyga: Approve by HICL or GPI-10.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IMMUNE GLOBULIN** requires the following rule(s) be met for approval:

A. **For Gammagard Liquid, Gamunex-C, Gammaked, Bivigam, Carimune NF Nanofiltered, Flebogamma DIF, Gammagard S-D, Gammaplex, Privigen, Octagam, or Panzyga for intravenous (IV) injection**, approval requires you to have ONE of the following diagnoses:
   1. Primary Immunodeficiency Disease (genetic disease where your immune system is weak)
   2. Idiopathic Thrombocytopenic Purpura (Low levels of the blood cells that prevent bleeding)
   3. Chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
   4. Multifocal Motor Neuropathy (nerve disorder with increasing muscle weakness and wasting)
   5. Kawasaki Syndrome (inflammation in the walls of blood vessels in the body)
   6. B-cell Chronic Lymphocytic Leukemia (blood and bone marrow cancer of immune cells) with Autoimmune Hemolytic Anemia (body destroys red blood cells more rapidly than it produces them), Immune Thrombocytopenic Purpura (decreased number of blood cells that prevent bleeding with increased easy bruising) OR Pure Red Cell Blood Aplasia (bone marrow stops making red blood cells)
   7. Guillain-Barre Syndrome (immune system attacks the nerves)
   8. Myasthenia Gravis (weakness and rapid fatigue of muscles under voluntary control)
   9. Autoimmune Graves' Ophthalmopathy (type of eye disease from having little to no thyroid)
   10. Cytomegalovirus-induced Pneumonitis related to a solid organ transplant (lung tissue inflammation) related to a solid organ transplant
   11. Prevention of bacterial infection in an HIV-infected child (human immunodeficiency virus)-infected child
   12. Reduction of secondary infections in pediatric HIV infections
   13. Dermatomyositis (inflammatory disease with muscle weakness and skin rash) or polymyositis (type of inflammatory muscle disease)
   14. Autoimmune uveitis (Birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
   15. Lambert-Eaton myasthenic syndrome (nerve disease in which the immune system attacks the body's own tissues)
   16. IgM (Immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (type of nerve damage)
   17. Stiff-man syndrome (nerve disorder with increasing muscle stiffness (rigidity) and repeated episodes of painful muscle spasms)
   18. Neonatal sepsis (blood infection in infants)
   19. Rotaviral enterocolitis (severe diarrhea among infants and young children)
   20. Toxic shock syndrome (life-threatening complication of certain bacterial infections)

   (Denial text continued on next page)

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

21. Enteroviral meningoencephalitis (Inflammation of the brain and surrounding tissues caused by a virus)
22. Toxic Epidermal Necrolysis or Stevens-Johnson syndrome (both are types of serious skin bacterial infections)
23. Autoimmune Mucocutaneous Blistering Disease (group of serious skin conditions that start with blisters on the skin) such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita

B. **For Asceniv, approval requires:**
   1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)
   2. You are 12 years of age or older
   3. You have tried any other TWO immunoglobulin products

C. **For Gamastan S-D, approval requires:**
   1. You are using the requested drug for prophylaxis (prevention) or passive immunization (immune response where antibodies are obtained from outside the body) of hepatitis A, measles, varicella, or rubella

D. **For Hizentra, approval requires:**
   1. The medication is only for subcutaneous (under the skin) use
   2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak) OR chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

E. **For Cuvitru, Hyqvia, Cutaquig, or Xembify, approval requires:**
   1. The medication is only for subcutaneous (under the skin) use
   2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

F. **For Gammagard Liquid, Gamunex-C, or Gammaked for subcutaneous use, approval requires:**
   1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IMMUNE GLOBULIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for the drugs listed in this guideline.

REFERENCES

- Bivigam [Prescribing Information]. Biotest Pharmaceuticals Co.: Boca Raton, FL. January 2017.
- Carimune NF [Prescribing Information]. CSL Behring LLC: Kankakee, IL. September 2013.
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