ATRIO HEALTH PLANS

IVIG (Intravenous Immunoglobulins [IgG])

Preferred: Privigen J1459**, Gamunex** J1561**, Octagam** J1568, **Flebogamma** J1572

Non-preferred: Cutaquig J1551**, Alyglo** J1552, **Asceniv [non-lyophilized]** J1554**, Cuvitru** J1555**, Bivigam** J1556**, Gammaplex** J1557**, Xembify** J1558**, Hizentra** J1559**, Gamastan** J1460/J1560**, Vivaglobin** J1562**, IVIG powder** J1566**, Gammagard** J1569**, HyQvia** J1575**, , Panzyga** J1576**, IVIG liquid** J1599

Prior Authorization Step Therapy **Medicare Part B Request Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)
Requests for a non-preferred intravenous immunoglobulin agent may be approved when the following criteria are met:

☐ Documentation is provided that patient has had a trial and inadequate response or intolerance to TWO preferred intravenous Ig agents;
IVIG Agent 1: _____ Date: _____
IVIG Agent 2: _____ Date: _____ OR

☐ Documentation is provided that the preferred Ig agents are not acceptable due to concomitant clinical condition(s), which requires an Ig agent with specific properties. Examples include, but not limited to the following:

☐ Severe IgA deficiency (<7 mg/dL of IgA), or IGA deficiency with antibodies against IgA, requiring agent with very low IGA content; OR

☐ Hypersensitivity, as manifested by a severe systemic/allergic or anaphylactic reaction, to any ingredient which is not also present in the requested non-preferred agent; OR
☐ Clinically significant reaction, including, but not limited to, hemolysis or renal dysfunction/impairment, that may be lessened by use of a non-preferred agent with different properties; OR
☐ The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label use policy for the prescribed indication and the requested non-preferred agent does.
☐ Other: _____

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**
If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)
☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**
☐ Patient had an adequate response or significant improvement while on this medication.
If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – IVIG (Intravenous Immunoglobulin) PA

Drug Name(s):

GAMUNEX	**OCTAGAM**	**PRIVIGEN**	**VIVAGLOBIN**
ASCENIV	**BIVIGAM**	**CUTAQUIG**	**CUVITRU**
FLEBOGAMMA	**GAMMAGARD**	**GAMMAPLEX**	**ALYGLO**
HIZENTRA	**HYQVIA**	**GAMASTAN**	**PANZYGA**
IVIG LIQUID	**IVIG POWDER**	**XEMBIFY**	

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least TWO of the formulary alternatives: **Flebogamma**, **Gamunex, Octagam, Privigen** OR
   - There is clinical documentation stating formulary alternatives are contraindicated.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 12 months

FDA Indications:

Alyglo, Asceniv, Bivigam, Cuvitru, Flebogamma, Gammagard, Gammaplex, Hizentra, HyQvia, IVIG Liquid, IVIG Powder, Panzyga, Xembify

- Bacterial infectious disease; Prophylaxis - B-cell chronic lymphocytic leukemia
- Dermatomyositis
- Hepatitis A; Prophylaxis
- Inflammatory demyelinating polyradiculoneuropathy, chronic
- Kawasaki disease
- Measles; Prophylaxis
- Measles; Prophylaxis – Post-exposure prophylaxis, When used for existing FDA approved use
- Motor neuropathy with multiple conduction block
- Post-exposure prophylaxis - Rubella in pregnancy
- Primary immune deficiency disorder
- Thrombocytopenic purpura, Idiopathic and chronic immune
- Varicella, When varicella-zoster immune globulin is unavailable; Prophylaxis

Off-Label Uses:

IVIG Products

- Acquired epidermolysis bullosa
- Autoimmune hemolytic anemia

- Autoimmune neutropenia
- Bone marrow transplant; Adjunct
- Bullous pemphigoid
- Clostridium difficile colitis (pediatric only)
- Cytomegalovirus infection; Treatment and Prophylaxis
- Desensitization therapy – Transplantation of heart
- Disorder of nervous system (pediatric only)
- Disseminated encephalomyelitis, acute (pediatric only)
- Epilepsy (pediatrics only)
- Guillain-Barre syndrome
- Herpes gestations
- HIV infection (pediatric only)
- Kidney disease
- Linear IgA dermatosis
- Lumbosacral radiculoplexus neuropathy due to diabetes mellitus
- Multisystem inflammatory syndrome in children, Associated with SARS-CoV-2 (COVID-19) (pediatric only)
- Myasthenia gravis
- Neonatal jaundice
- Ocular cicatricial pemphigoid
- Polyarteritis nodosa
- Post-transplant lymphoproliferative disorder
- Pyoderma gangrenosum
- Pemphigus vulgaris
- Renal transplant rejection
- Respiratory syncytial virus infection
- Stiff-person syndrome
- Toxic shock syndrome
- Transplantation of heart, Antibody-mediated rejection, adjunctive treatment
- Transplant of kidney, Pretransplant desensitization of highly sensitized patients
- Uveitis
- von Willebrand disorder

Step Therapy Drug(s) and FDA Indications:

Gamunex, Octagam, Privigen

Prescribed for ONE of the following diagnoses:

- Bacterial infectious disease; Prophylaxis - B-cell chronic lymphocytic leukemia
- Dermatomyositis
- Hepatitis A; Prophylaxis
- Inflammatory demyelinating polyradiculoneuropathy, chronic
- Kawasaki disease
- Measles; Prophylaxis
- Measles; Prophylaxis – Post-exposure prophylaxis, When used for existing FDA approved use
- Motor neuropathy with multiple conduction block
- Post-exposure prophylaxis - Rubella in pregnancy
- Primary immune deficiency disorder
- Thrombocytopenic purpura, Idiopathic and chronic immune
- Varicella, When varicella-zoster immune globulin is unavailable; Prophylaxis

Age Restrictions:

N/A

Other Clinical Considerations:

For patients at risk of thrombosis, renal dysfunction or renal failure, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout

https://careweb.careguidelines.com/ed24/ac/ac04_037.htm