**Intravenous Immune Globulin (IVIG) (J1566, J1599)**

**Specific brand names:** Flebogamma® (J1572), Gammagard® liquid (J1569), Gammaked® (J1569), Gammaplex® (J1557), Gammunex® (J1561), Gammaplex (J1557), Octagam® (J1568), Privigen® (J1459), Cytogam® (J0850), Bivigam® (J1556)

***MD DETERMINATION FORM***

**Patient Name and ID Number:**

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| **I. Determination :**  **Approve**  **Deny**  **Modify** | |
| **II. Principle Reason (Main Reason for Determination)** | |
| The patient’s condition does not meet the criteria for the use of intravenous immune globulin (IVIG) as established by the Blue Shield of California Pharmacy and Therapeutics Committee, the manufacturer, and/or the FDA indications for usage. (EOB A460)  The medical need for intravenous immune globulin (IVIG) has not been established following review of the documentation submitted. (A009)  The use of intravenous immune globulin (IVIG) in this condition is considered to be investigational or experimental as it is not in accord with BSC Injectable Medication Policy. (A461)  Other: | |
| **III. Clinical Rationale (Supporting Rationale for Principle Reason):** | |
| **INITIATION OF THERAPY**  **Autoimmune mucotaneous blistering diseases (AMBDs)**  The documentation does not indicate that laboratory testing was done to confirm your diagnosis. Coverage of IVIG requires that laboratory testing be done on the tissue or fluid from a lesion to establish the diagnosis.  The documentation provided by your physician does not indicate that you have tried an immunosuppressant (a medication that reduces the activity of your immune system). If you are not able to take these agents, your physician should submit chart notes explaining why they are not an option for you.  The documentation provided by your physician does not indicate that you have taken a corticosteroid medication either by mouth or injection. If you are not able to take these agents, your physician should submit chart notes explaining why they are not a option for you.  **Chronic Lymphocytic Leukemia**  The documentation provided by your physician does not indicate that you have a primary diagnosis of chronic lymphocytic leukemia (CLL) with either a history of low gammaglobulin ( IgG) levels or a history of multiple bacterial infections.  **Chronic Inflammatory Demyelinating Polyneuropathy and its variants**  The documentation provided by your physician does not indicate that the diagnosis was confirmed by a neurologist using nerve conduction studies.  The documentation provided by your physician does not indicate that you have experienced at least 2 of the following: decrease in sensation or movement of your affected arm(s) or leg(s) that developed over at least 2 months, lack of reflexes in the affected arm(s) or leg(s), a biopsy showing clear evidence of nerve damage and repair (demyelination and remyelination), and a cerebrospinal fluid(CSF) lab showing a cell count less than 10/mm-3, or a CSF lab showing a cell count less than 50/mm-3 if you are HIV positive.  **Guillian-Barre Syndrome**  The documentation provided by your physician indicates it has been greater than 4 weeks since you were diagnosed with Guillian-Barre syndrome. American Academy of Neurology guidelines for treatment of Guillian-Barre syndrome state that IVIG treatment is most effective if it has been given within the first 4 weeks that you experience symptoms related to Guillian-Barre syndrome.  **Hematopoietic Stem Cell or Bone Marrow Transplant**  The documentation submitted by your physician indicates that you received your transplant more than 100 days ago. Coverage of IVIG more than 100 days after your transplant requires that your provider submit one of the following: a positive CMV test or an IgG lab less than 400mg/dl. You may also qualify for IVIG if you have a below normal IgG level plus either chronic graft-vs-host disease (GVHD) on steroids or GVHD with a lung infection.  **Hemolytic Anemia- Autoimmune**  The documentation provided by your physician does not indicate that you used steroid medications to treat your condition. IVIG may be approved for warm-type autoimmune hemolytic anemia when primary treatments like high dose steroids are not effective.  **HIV (pediatric)**  The documentation provided by your physician does not support a primary diagnosis of human immunodeficiency virus (HIV) with a history of symptomatic HIV or recurrent bacterial infections.  The documentation provided by your physician does not indicate that you have a CD4+ count greater than 200/mm3.  The documentation provided indicates that you are over 13 years of age. IVIG is supported for symptomatic HIV in patients 13 years old or younger.  **Idiopathic Thrombocytopenic Purpura**  The documentation provided by your physician does not indicate that you have a current platelet count less than 30,000/mcl. The American Society of Hematology recommends treatment of idiopathic thrombocytopenic purpura (ITP) once a platelet count falls below 30,000/mcl.  Recertification  The documentation provided by your physician does not indicate a medical rationale for continued use of IVIG for treatment of idiopathic thrombocytopenic purpura (ITP) past the initial 12 months of treatment. Please have the provider submit medical rationale for continued use of IVIG in this setting.  **Kawasaki Disease**  The documentation provided by your physician does not indicate that you are currently or will be on combination treatment with high dose aspirin and IVIG. IVIG may be approved for a patient for treatment of Kawasaki disease when given in combination with high dose aspirin.  **Multiple Myeloma**  The documentation provided by your physician does not indicate that you have experienced 2 or more significant infections or 1 life-threatening infection in the last year. IVIG may be approved for a patient with a diagnosis of multiple myeloma, when documentation is provided that the patient has experienced 2 or more significant infections or 1 life-threatening infection in the last year.  **Myasthenia Gravis**  The documentation provided by your physician does not indicate that IVIG is being prescribed by a neurologist specialist.  The documentation provided by your physician does not indicate that you have tried at least one of the following medications: corticosteroid, mycophenolate, azathioprine, cyclosporine, or cyclophosphamide. IVIG, when prescribed by a neurologist, may be approved after you have had a trial of at least one of the supported alternate therapies listed for treatment of myasthenia gravis.  **Polymyositis and Dermatomyositis**  The documentation provided by your physician does not indicate you have tried high dose corticosteroid medications. High dose corticosteroid therapy is supported as the primary treatment for this condition.  **Primary Immunodeficiency Disorders**  The documentation provided by your physician indicates that you have selective IgA deficiency or isolated IgG4 deficiency. Safety and efficacy of IVIG in these disorders has not established in peer-reviewed, published, scientific literature.  The documentation provided by your physician does not indicate that you have had at least two IgG lab levels that are either less than 500mg/dl each or lower than the average value would be for other people your age taking the same test.  The documentation provided by your physician appears to indicate that you are able to produce antibodies when you are exposed to antigens like diphtheria and tetanus toxoids or pneumococcal polysaccharide vaccine. IVIG is only indicated to replace antibodies when patients cannot or have a decreased ability to produce these antibodies.  The documentation provided by your physician does not indicate that you have a history of recurrent bacterial infections. IVIG is indicated to replace antibodies in patients who are experiencing repeat infections because of the low antibody levels in their bodies.  **General**  The clinical information reviewed does not contain a complete evaluation or work-up including       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  The dose and/or frequency requested is more than the maximum amount that can be approved.  Safety and efficacy of IVIG use for this diagnosis,      , is not established in peer-reviewed, published, scientific literature.  Other:  **Recertification (ITP and HSCT recertification parameters listed above)**  The efficacy of IVIG in this case has not been demonstrated because      \_\_\_\_.  The dose and/or frequency requested is more than the maximum amount that can be approved.  The safety and efficacy or IVIG **retreatment** in this diagnosis,      , is not supported by peer-reviewed, published, scientific literature.  The safety and efficacy of IVIG treatment longer than       weeks/year(s) in this diagnosis       is not established in peer-reviewed, published, scientific literature. | |
| **IV. Modification** | |
| Approve IVIG      mg/kg (     GM) every       week(s)/month(s) for      doses/     year effective       through      . | |
| The subscriber’s plan does provide for standard services and medication. |

PA Stamp

## Physician Advisor’s Signature

Intravenous immune globulin\_IVIG\_MD Determination Form 06.18.15.doc