Immune Globulins

Prior Authorization Request

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*ft* _____*inches*

Site of Service Questions:

A. Indicate the site of service requested: ***If using Ig subcutaneously, please skip to Criteria Questions.***
- ❑ Outpatient hospital
- ❑ Home infusion
- ❑ Ambulatory surgical
- ❑ Physician office
- ❑ Pharmacy
- ❑ Inpatient hospital

B. Is the patient less than 21 years old or 65 years of age or older?
- ❑ Yes – less than 21 years old
- ❑ Yes – age 65 years or older, *skip to Criteria Questions*
- ❑ No, *Skip to Question D.*

C. After tolerance of the medication has been established, would this patient be a candidate to receive Ig therapy in a setting other than the hospital? *Indicate and skip to Criteria Questions* ❑ Yes ❑ No

D. Is the Ig being requested to treat an urgent medical condition?
- ❑ Yes - Myasthenic crisis with respiratory impairment, *skip to Criteria Questions*
- ❑ Yes - Acute ITP with bleeding, *skip to Criteria Questions*
- ❑ Yes - Kawaski disease, *skip to Criteria Questions*
- ❑ Yes - Guillian-Barre syndrome, *skip to Criteria Questions*
- ❑ Yes – Other_____, *skip to Criteria Questions*
- ❑ No

E. Is the request for a new therapy start or is this a new branded product of Ig that the patient has not received previously or is this a continuation of an existing treatment?
- ❑ This is a new therapy start, *skip to Criteria Questions*
- ❑ This is a new branded product of Ig, *skip to Criteria Questions*
- ❑ This is a continuation of existing treatment

F. Has the patient experienced moderate to severe adverse reactions with Ig use that have not responded to conventional interventions e.g. acetaminophen, steroids, diphenhydramine, fluids or other pre-medications to immune globulin therapy? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Criteria Questions* ❑ No

G. Does the patient have laboratory confirmed autoantibodies to IgA? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes, *skip to Criteria Questions* ❑ No

H. Has the patient previously experienced a severe adverse event during or immediately after an infusion including but not limited to: anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes, *skip to Criteria Questions* ❑ No

I. Does the patient have an inability to tolerate a large volume load and the dose cannot be divided into several smaller infusions? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Criteria Questions* ❑ No

J. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Criteria Questions* ❑ No

K. Does the patient have severe venous access issues that require the use of a phlebotomist? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes, *skip to Criteria Questions* ❑ No

L. Has the patient's home been previously determined to be inappropriate for home infusion by a social worker, case manager, or previous home care nurse assessment AND other non-hospital sites of service are not within a reasonable distance from the patient's home? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes ❑ No

Criteria Questions:

1. What drug is being prescribed?
❑ Bivigam ❑ Carimune NF ❑ Flebogamma DIF ❑ Gammagard Liquid ❑ Gammagard S/D ❑ Gammaked
❑ Gammaplex ❑ Gamunex-C ❑ Octagam ❑ Privigen ❑ Other _____

2. If applicable, will Gammagard Liquid, Gamunex-C, or Gammaked be administered subcutaneously?
❑ Yes ❑ No

3. What is the patient's diagnosis?
❑ Primary immunodeficiency (eg, common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency, Wiskott-Aldrich syndrome)
❑ Chronic inflammatory demyelinating polyneuropathy (CIDP)
❑ Multifocal motor neuropathy
❑ Dermatomyositis
❑ Polymyositis
❑ Guillain-Barré syndrome
❑ Myasthenia gravis
❑ Lambert-Eaton myasthenic syndrome
❑ Stiff-person syndrome
❑ Immune thrombocytopenic purpura (ITP)
❑ Parvovirus B19-induced pure red cell aplasia
❑ Kawasaki syndrome (pediatric)
❑ Fetal/neonatal alloimmune thrombocytopenia
❑ Human immunodeficiency virus (HIV) infection
❑ B-cell chronic lymphocytic leukemia (CLL)
❑ Bone marrow transplant/hematopoietic stem cell transplant recipient
❑ Other _____

4. What is the ICD-10 code? _____

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Primary Immunodeficiency

5. Is the patient currently receiving immune globulin therapy (intravenous or subcutaneous) through health insurance? **Note: If the patient is receiving immune globulin therapy (intravenous or subcutaneous) through samples or a manufacturer's patient assistance program, please answer No.* ❑ Yes ❑ No *If No, skip to #10*

6. Has the patient experienced a reduction in the frequency of bacterial infections since starting immune globulin therapy? ❑ Yes ❑ No

7. Does the prescriber measure trough IgG levels at least once per year? ❑ Yes ❑ No

8. ***ACTION REQUIRED:*** Please indicate and attach a copy of the current (on-treatment) trough IgG level (if applicable).
   a) Trough IgG (total) level: _____ mg/dL
   b) Is the trough IgG level at or above the lower normal reference range for age? ❑ Yes ❑ No
   c) Is a trough IgG level not applicable for the patient's diagnosis? ❑ Yes ❑ No

9. If applicable, will the prescriber re-evaluate the dose of immune globulin and consider a dose adjustment (when clinically appropriate)? ❑ Yes ❑ No ❑ Not applicable/not clinically appropriate

10. What is the specific immunodeficiency disorder?
    ❑ Severe combined immunodeficiency (SCID), ***specify:*** _____
    ❑ Congenital agammaglobulinemia (eg, X-linked or autosomal recessive agammaglobulinemia)
    ❑ Wiskott-Aldrich syndrome
    ❑ DiGeorge syndrome
    ❑ Ataxia-telangiectasia
    ❑ Other non-SCID combined immunodeficiency disorder, ***specify:*** _____
    ❑ Common variable immunodeficiency (CVID)
    ❑ Hypogammaglobulinemia (unspecified)
    ❑ Selective IgA deficiency
    ❑ Selective IgM deficiency
    ❑ IgG subclass deficiency
    ❑ Specific antibody deficiency
    ❑ Other predominant antibody deficiency disorder, ***specify:*** _____
    ❑ Other immunodeficiency disorder/none of the above, ***specify*****:** _____

11. ***ACTION REQUIRED:*** Please indicate and attach a copy of the following **pre-treatment** laboratory information (where applicable):
    IgG (total) level: _____ mg/dL
    a) Is IgG (total) level within the normal reference range? ❑ Yes ❑ No
    b) If No, is the IgG level greater than or equal to (≥) 2 SD below the mean for age? ❑ Yes ❑ No

    IgG subclass levels:
    a) IgG1 _____ mg/dL
    b) IgG2 _____ mg/dL
    c) IgG3 _____ mg/dL
    d) Other_____
    e) Are the IgG subclass levels within the normal reference range? ❑ Yes ❑ No
    f) If No, is the level(s) greater than or equal to (≥) 2 SD below the mean for age? ❑ Yes ❑ No
    g) Were IgG subclass levels measured on at least 2 different occasions? ❑ Yes ❑ No

    IgA level: _____ mg/dL
    a) Is the IgA level within the normal reference range? ❑ Yes ❑ No

    IgM level: _____ mg/dL
    a) Is the IgM level within the normal reference range? ❑ Yes ❑ No

12. If applicable, was the diagnosis confirmed by molecular or genetic testing? ***ACTION REQUIRED: If Yes, attach laboratory report or other medical record that shows the results of molecular/genetic testing.***
    ❑ Yes ❑ No ❑ Not applicable to diagnosis

13. *If patient is at least 6 years of age,* did the patient have protective antibody levels (at least 1.3 mcg/mL) for at least 70% of serotypes in the vaccine? ❑ Yes ❑ No

14. *If patient is 2 to 5 years of age,* did the patient have protective antibody levels (at least 1.3 mcg/mL) for at least 50% of serotypes in the vaccine? ❑ Yes ❑ No

15. Has the patient demonstrated an impaired antibody response to vaccination with a pneumococcal polysaccharide vaccine? ***ACTION REQUIRED: If Yes, attach laboratory report with post-vaccination titers.***
    ❑ Yes ❑ No ❑ Not applicable
16. Have other causes of immune deficiency been excluded (eg, drugs, infectious disease, malignancy)?
    ❑ Yes ❑ No ❑ Not applicable to diagnosis

17. Does the patient have a history of recurrent bacterial infections (eg, pneumonia, otitis media, sinusitis, sepsis, gastrointestinal infections)? ❑ Yes ❑ No

Neurologic Indications

Section B: Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

18. Is the patient currently receiving IVIG treatment through health insurance? **Note: If the patient is receiving IVIG therapy through samples or a manufacturer's patient assistance program, please answer No.*
    If Yes, skip to #24 ❑ Yes ❑ No
19. Does the patient have moderate to severe functional disability? ❑ Yes ❑ No
20. Were electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS]) performed to confirm the diagnosis? ***ACTION REQUIRED: If Yes, attach EMG or NCS test results.*** ❑ Yes ❑ No
21. Were the results consistent with multifocal demyelinating abnormalities? ❑ Yes ❑ No
22. Was evaluation of cerebrospinal fluid (CSF) performed to confirm the diagnosis?
    ❑ Yes ❑ No *If No, no further questions*
23. Did the results show elevated CSF protein? ❑ Yes ❑ No *No further questions*
24. Has the patient demonstrated significant improvement in disability and/or maintenance of improvement since starting IVIG therapy? ❑ Yes ❑ No
25. What is the duration of treatment with IVIG? _____ years / months
26. *If greater than or equal to 1 year*, if the patient is clinically stable, has the dose of IVIG been tapered and/or treatment withdrawn to determine whether continued use of IVIG is necessary?
    ❑ Yes ❑ No ❑ Not appropriate/not clinically stable
27. Is IVIG being used at the lowest effective dose and frequency? ❑ Yes ❑ No

Section C: Multifocal Motor Neuropathy (MMN)

28. Is the patient currently receiving IVIG treatment through health insurance? **Note: If the patient is receiving IVIG therapy through samples or a manufacturer's patient assistance program, please answer No.*
    If Yes, skip to #41 ❑ Yes ❑ No
29. Does the patient have weakness without objective sensory loss in 2 or more nerves? ❑ Yes ❑ No
30. Were electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS]) performed to confirm the diagnosis? ***ACTION REQUIRED: If Yes, attach EMG or NCS test results.*** ❑ Yes ❑ No
31. Were the results consistent with motor conduction block? ❑ Yes ❑ No
32. Were the results of sensory nerve conduction studies normal? ❑ Yes ❑ No

Section D: Dermatomyositis (DM) or Polymyositis (PM)

33. Is the patient currently receiving IVIG treatment through health insurance? **Note: If the patient is receiving IVIG therapy through samples or a manufacturer's patient assistance program, please answer No.*
    If Yes, skip to #41 ❑ Yes ❑ No
34. Was the diagnosis established by the presence of specific clinical features (eg, proximal weakness, rash) AND elevated muscle enzyme levels? ❑ Yes ❑ No
35. Were electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS]) performed to confirm the diagnosis? ***ACTION REQUIRED: If Yes, attach EMG or NCS test results.*** ❑ Yes ❑ No
36. Were the results consistent with a diagnosis of dermatomyositis or polymyositis? ❑ Yes ❑ No
37. Was muscle biopsy performed to confirm the diagnosis? ❑ Yes ❑ No *If No, skip to #39*
38. Were the results consistent with a diagnosis of dermatomyositis or polymyositis? ❑ Yes ❑ No
39. Was standard first-line treatment (corticosteroids or immunosuppressants) tried but was unsuccessful or not tolerated?
    If Yes, no further questions ❑ Yes ❑ No

40. Is the patient unable to receive standard first-line therapy because of a contraindication or other clinical reason? ❑ Yes ❑ No

For patients with MMN, DM or PM continuing with IVIG therapy

41. Has the patient demonstrated significant improvement in disability and/or maintenance of improvement since starting IVIG therapy? ❑ Yes ❑ No *No further questions*

Section E: Guillain-Barre Syndrome

42. Is physical mobility severely affected such that the patient requires an aid to walk? ❑ Yes ❑ No

43. Will IVIG therapy be initiated within 2 weeks of symptom onset? ❑ Yes ❑ No

Section F: Myasthenia Gravis

44. Is IVIG prescribed for any of the following reasons?
    - ❑ Acute exacerbation/crisis
    - ❑ Pre-operative management (eg, prior to thymectomy)
    - ❑ Worsening weakness
    - ❑ Stable on maintenance therapy
    - ❑ Other _____

45. Does the patient have severe swallowing difficulty and/or respiratory failure? ❑ Yes ❑ No

46. Does the patient have weakness with an increase in any of the following symptoms: diplopia, ptosis, blurred vision, difficulty speaking (dysarthria), difficulty swallowing (dysphagia), difficulty chewing, impaired respiratory status, fatigue, or limb weakness? ❑ Yes ❑ No

ITP and Other Hematologic Indications

Section G: Immune Thrombocytopenic Purpura (ITP)

47. Is the patient a pregnant woman? ❑ Yes ❑ No
    If Yes, provide estimated date of delivery and no further questions: _____

48. Is the patient an adult with refractory ITP after splenectomy? *If Yes, skip to #51* ❑ Yes ❑ No

49. What is the classification of ITP?
    - ❑ Newly-diagnosed ITP (diagnosed within the past 3 months)
    - ❑ Previously untreated ITP (initial therapy)
    - ❑ Chronic or persistent ITP (greater than or equal to [≥] 3 months from diagnosis)
    - ❑ ITP unresponsive to first-line treatment
    - ❑ Other _____

50. What is the current pre-treatment platelet count? _____ /mcL (x 10^9/L)
    ACTION REQUIRED: Attach laboratory report with current platelet count.

51. Does the patient have significant bleeding symptoms (eg, mucosal bleeding or other moderate to severe bleeding)? ❑ Yes ❑ No

52. Is the patient at high risk for bleeding or does the patient require a rapid increase in platelets?
    ACTION REQUIRED: If Yes, indicate the risk factors for bleeding or reason for a rapid increase in platelets.
    - ❑ Undergoing a medical or dental procedure where blood loss is anticipated
    - ❑ Comorbidity (eg, peptic ulcer disease or hypertension)
    - ❑ Mandated anticoagulation therapy
    - ❑ Profession or lifestyle predisposes the patient to trauma (eg, construction worker, fireman, professional athlete)
    - ❑ Other _____
    - ❑ No, not at high risk or does not require rapid increase in platelets

53. Will IVIG be used alone (monotherapy) or given in combination with corticosteroid therapy? ❑ Yes ❑ No

54. Does the patient have relapsed ITP after a previous response to IVIG therapy? ❑ Yes ❑ No

55. Does the patient have a history of inadequate response, intolerance or a contraindication to corticosteroid or anti-D therapy? ❑ Yes ❑ No

Section H: Fetal/Neonatal Alloimmune Thrombocytopenia

56. Is the patient a pregnant woman? ❑ Yes ❑ No

Indications related to CLL, HIV, or BMT/HSCT

57. Is the patient currently receiving IVIG treatment through health insurance? **Note: If the patient is receiving IVIG therapy through samples or a manufacturer's patient assistance program, please answer No.*
If Yes, skip to #66 ❑ Yes ❑ No

58. What is the patient's pre-treatment IgG level? _____ mg/dL ***ACTION REQUIRED: Attach laboratory report with the pre-treatment IgG level.***

Continue to additional questions below based on the patient's diagnosis.

Section I: B-Cell CLL and BMT/HSCT Transplant Recipients

59. Is IVIG prescribed for prophylaxis of bacterial infections? ❑ Yes ❑ No

60. Does the patient have a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization? ❑ Yes ❑ No

61. If applicable, has the patient received a bone marrow/hematopoietic stem cell transplant within the past 100 days? ❑ Yes ❑ No

Section J: Pediatric HIV Infection

62. Is IVIG prescribed for prophylaxis of bacterial infections?
❑ Yes, primary prophylaxis ❑ Yes, secondary prophylaxis ❑ No, not used for prophylaxis of bacterial infections

63. Does the patient have a history of recurrent bacterial infections (greater than [>] 2 serious bacterial infections in a 1-year period)? ❑ Yes ❑ No

64. Is the patient unable to take combination antiretroviral therapy? ❑ Yes ❑ No

65. Was prophylaxis with antibiotics (eg, trimethoprim-sulfamethoxazole) tried but was not effective? ❑ Yes ❑ No

For patients with CLL, HIV or BMT/HSCT recipients continuing with IVIG therapy

66. Has the patient experienced a reduction in the frequency of bacterial infections since starting IVIG therapy? ❑ Yes ❑ No

Section K: Stiff-person syndrome

67. Has the patient experienced an inadequate response or intolerance, or has a contraindication to first-line therapy such as a benzodiazepine (eg, diazepam) and/or baclofen? ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**