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 **1-888-877-0518.** 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.

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

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

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

Required Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*cm*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical* ❑ *Home* ❑ *Inpatient Hospital* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office* ❑ *Pharmacy*

Site of Service Questions: ***If using Ig subcutaneously, please skip to Criteria Questions.***

A. Indicate the site of service requested:
- ❑ On Campus Outpatient Hospital
- ❑ Home infusion, *skip to Clinical Questions*
- ❑ Ambulatory surgical, *skip to Clinical Questions*
- ❑ Off Campus Outpatient Hospital
- ❑ Physician office, *skip to Clinical Questions*
- ❑ Pharmacy, *skip to Clinical Questions*
- ❑ Inpatient hospital, *skip to Clinical Questions*

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 - Kawasaki disease, *skip to Criteria Questions*
- ❑ Yes - Guillain-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 ❑ Flebogamma DIF ❑ Gammagard Liquid ❑ Gammagard S/D ❑ Gammaked ❑ Gammaplex
   ❑ Gamunex-C ❑ Octagam ❑ Panzyga ❑ Privigen ❑ Other _____

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

3. What is the diagnosis?
   ❑ Primary immunodeficiency (eg, common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency, Wiskott-Aldrich syndrome)
   ❑ Myasthenia gravis
   ❑ Chronic inflammatory demyelinating polyneuropathy (CIDP)
   ❑ Dermatomyositis
   ❑ Polymyositis
   ❑ Immune thrombocytopenic purpura (ITP)
   ❑ Multifocal motor neuropathy
   ❑ Guillain-Barré syndrome
   ❑ Lambert-Eaton myasthenic syndrome
   ❑ Parvovirus B19-induced pure red cell aplasia
   ❑ Kawasaki syndrome (pediatric)
   ❑ Fetal/neonatal alloimmunethrombocytopenia
   ❑ Stiff-person syndrome
   ❑ Human immunodeficiency virus (HIV) infection
   ❑ B-cell chronic lymphocytic leukemia (CLL)
   ❑ Bone marrow transplant/hematopoietic stem cell transplant recipient
   ❑ Immune checkpoint inhibitor related nervous system toxicity
   ❑ 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 this request for continuation of immune globulin therapy (intravenous or subcutaneous)?
   ❑ 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 ❑ Not applicable for diagnosis

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
   No further questions

10. What is the specific immunodeficiency disorder?
    ❑ Common variable immunodeficiency (CVID)
    ❑ Hypogammaglobulinemia (unspecified) or other predominant antibody deficiency disorder, ***specify:*** _____
    ❑ IgG subclass deficiency
    ❑ Selective IgA deficiency
    ❑ Selective IgM deficiency
    ❑ Severe combined immunodeficiency (SCID), ***specify:*** _____
    ❑ Other non-SCID combined immunodeficiency disorder, ***specify:*** _____
    ❑ Congenital agammaglobulinemia (eg, X-linked or autosomal recessive agammaglobulinemia)
    ❑ Specific antibody deficiency
    ❑ 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 diagnosis is severe combined immunodeficiency,* are maternal T cells present in the circulation?
If Yes, no further questions ❑ Yes ❑ No

14. *If diagnosis is severe combined immunodeficiency,* what is the patient's CD3 T cell count? _____ per microliter ***ACTION REQUIRED: Attach a copy of the laboratory report with lymphocyte subset enumeration by flow cytometry.*** *No further questions*

15. *If diagnosis is common variable immunodeficiency,* have other causes of immune deficiency been excluded (eg, drugs, infectious disease, malignancy)? ❑ Yes ❑ No

16. Was the immune globulin therapy initiated in the hospital setting? ❑ Yes ❑ No

17. 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

18. 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)

19. Is this request for continuation of immune globulin therapy (intravenous)? *If Yes, skip to #22* ❑ Yes ❑ No

20. Does the patient have moderate to severe functional disability? ❑ Yes ❑ No

21. Were electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS]) and the evaluation of cerebrospinal fluid (when available) performed to confirm the diagnosis? ***ACTION REQUIRED: If Yes, attach a copy of the EMG or NCS test results.*** ❑ Yes ❑ No *No further questions*

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

23. Is IVIG being used at the lowest effective dose and frequency? ❑ Yes ❑ No

Section C: Multifocal Motor Neuropathy (MMN)

24. Is this request for continuation of immune globulin therapy (intravenous)? *If Yes, skip to #32* ❑ Yes ❑ No

25. Does the patient have weakness without objective sensory loss in 2 or more nerves? ❑ Yes ❑ No

26. Were electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS]) performed to confirm the diagnosis? ***ACTION REQUIRED: If Yes, attach a copy of the EMG or NCS test results.***
❑ Yes ❑ No

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

27. Is this request for continuation of immune globulin therapy (intravenous)? *If Yes, skip to #32* ❑ Yes ❑ No

28. Was the diagnosis established by the presence of specific clinical features (eg, proximal weakness, rash) AND elevated muscle enzyme levels? ❑ Yes ❑ No

29. Were electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS]) and the muscle biopsy (when available) performed to confirm the diagnosis? ***ACTION REQUIRED: If Yes, attach a copy of the EMG or NCS test results.*** ❑ Yes ❑ No

30 Was standard first-line treatment (corticosteroids or immunosuppressants) tried but was unsuccessful or not tolerated? *If Yes, no further questions* ❑ Yes ❑ No

31. 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

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

Section E: Myasthenia Gravis

33. What is the primary reason IVIG is being prescribed?
❑ Acute exacerbation/crisis ❑ Pre-operative management (eg, prior to thymectomy)
❑ Worsening weakness ❑ Refractory myasthenia gravis *Skip to #36*
❑ Other _____

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

35. 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 *No further questions*

36. Has the patient tried and failed 2 or more of standard therapies (eg, corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab)? ❑ Yes ❑ No

Section F: Lambert-Eaton Myasthenic Syndrome

37. Has the diagnosis been confirmed by neurophysiology studies (e.g., electromyography) or a positive anti- P/Q type voltage-gated calcium channel antibody test? ***ACTION REQUIRED: If Yes, please attach a copy of the laboratory report, neurophysiology study report or other supporting medical record(s).***
❑ Yes - Neurophysiology studies
❑ Yes - Positive anti- P/Q type voltage-gated calcium channel antibody test
❑ No

ITP and Other Hematologic Indications

Section G: Immune Thrombocytopenic Purpura (ITP)

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

39. Is the patient an adult with refractory ITP after splenectomy? *If Yes, skip to #41* ❑ Yes ❑ No

40. 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 _____

41. What is the current pre-treatment platelet count? _____ /mcL (x 10^9/L)

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

43. 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

44. Will IVIG be used alone (monotherapy) or given in combination with corticosteroid therapy?
    If Yes, no further questions ❑ Yes ❑ No

45. Does the patient have relapsed ITP after a previous response to IVIG therapy?
    If Yes, no further questions ❑ Yes ❑ No

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

Indications related to CLL, HIV, BMT/HSCT, or Immune Checkpoint Inhibitor-Related Adverse Events

47. Is this request for continuation of immune globulin therapy (intravenous)? *If Yes, skip to #54* ❑ Yes ❑ No

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

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

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

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

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

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

Section I: Pediatric HIV Infection

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

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

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

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

Section J: Immune Checkpoint Inhibitor-Related Adverse Events

55. Has the patient experienced a moderate or severe adverse event to a PD-1 inhibitor (e.g., pembrolizumab, nivolumab) or PD-L1 inhibitor (e.g., atezolizumab, avelumab, durvalumab)? ❑ Yes ❑ No

56. Is the offending drug being temporarily held or has it been discontinued permanently? ❑ Yes ❑ No

57. Which of the following adverse events did the patient experience?
❑ Pneumonitis ❑ Myasthenia gravis ❑ Peripheral neuropathy ❑ Encephalitis ❑ Transverse myelitis
❑ Other _____

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)**