Immune Globulins Subcutaneous and Intravenous

HMSA - Prior Authorization Request

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 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** 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:** _____
Patient's Phone Number: _____
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*

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

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Criteria Questions:

1. ***Indicate where the drug is being dispensed:***
   ❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
   ❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
   ❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
   ❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
   ❑ Psychiatric Facility ❑ Pharmacy ❑ Other

2. ***Indicate where the drug is being administered:***
   ❑ Ambulatory surgical ❑ Home ❑ Inpatient Hospital
   ❑ Office ❑ Outpatient Hospital ❑ Pharmacy

3. What is the requested product?

❑ Asceniv	❑ Bivigam
❑ Gammaplex	❑ Carimune
❑ Gamunex-C	❑ Cutaquig
❑ Hizentra	❑ Cuvitru
❑ HyQvia	❑ Flebogamma
❑ Octagam	❑ Gammagard Liquid
❑ Panzyga	❑ Gammagard S/D
❑ Privigen	❑ Gammaked
❑ Xembify	❑ Other_____

4. What is the ICD-10 code? _____

5. Will Gammagard Liquid, Gamunex-C or Gammaked be administered subcutaneously?
   ❑ Yes ❑ No ❑ Not Applicable

6. What is the diagnosis?
   ❑ Primary immunodeficiency
   (includes congenital agammaglobulinemia, X-lined agammaglobulinemia, hypogammaglobulinemia, common variable immunodeficiency, X-linked immunodeficiency with hyper IgM syndrome, severe combined immunodeficiency, and Wiskott-Aldrich syndrome)
   ❑ Secondary immunodeficiency due to drugs/biologic agents, underlying disease, environmental exposure, or other causes
   ❑ Bone marrow/hematopoietic stem cell transplant recipient, *Skip to diagnosis section*
   ❑ Human immunodeficiency virus (HIV) infection, *Skip to diagnosis section*
   ❑ Chronic lymphocytic leukemia (CLL)
   ❑ Chronic inflammatory demyelinating polyneuropathy (CIDP)
   ❑ Multifocal motor neuropathy
   ❑ Guillain-Barre syndrome, *Skip to diagnosis section*
   ❑ Dermatomyositis
   ❑ Myasthenia gravis
   ❑ Pemphigus vulgaris or pemphigus foliaceus, *Skip to diagnosis section*
   ❑ Bullous pemphigoid or mucous membrane pemphigoid, *Skip to diagnosis section*
   ❑ Epidermolysis bullosa acquisita, *Skip to diagnosis section*
   ❑ Idiopathic thrombocytopenic purpura (ITP), *No further questions*
   ❑ Fetal alloimmune thrombocytopenia, *No further questions*
   ❑ Kawasaki syndrome, *Skip to diagnosis section*
   ❑ Other _____

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7. Is this request for a new start or continuation of Subcutaneous Immune Globulin (SCIG)/ Intravenous Immune Globulin (IVIG) therapy?
   If New start, skip to diagnosis section ❑ New start ❑ Continuation

8. Was SCIG/IVIG previously authorized by HMSA/CVS for this member?
   ❑ Yes
   ❑ No
   ❑ Unknown

Please complete the following section based on the member's diagnosis.

Section A: Primary Immunodeficiency or Secondary Immunodeficiency

NEW START

9. Does the member have laboratory evidence of immunoglobulin deficiency, defined as any of the following?
   Action Required: Please attach a copy of the laboratory report. *Indicate any/all that apply:*
   ❑ Agammaglobulinemia (total IgG less than 200 mg/dL)
   ❑ Persistent hypogammaglobulinemia (total IgG less than 400 mg/dL, or at least two standard deviations below normal, on at least two occasions)
   ❑ Absence of B lymphocytes
   ❑ None of the above

10. Does the member have a documented inability to mount an adequate response to inciting antigens, defined as any of the following? ***Action Required: Please attach a copy of the laboratory report.*** *Indicate any/all that apply:*
    ❑ Lack of appropriate rise in antibody titer following provocation with a polysaccharide antigen. *(ie, an adequate response to the pneumococcal vaccine may be defined as at least a 4-fold increase in titers for at least 50% of serotypes tested)*
    ❑ Lack of appropriate rise in antibody titer following provocation with a protein antigen. *(ie, an adequate response to tetanus/diphtheria vaccine may be defined as less than a 4-fold rise in titers 3-4 weeks after vaccine administration)*
    ❑ None of the above

11. Does the member have persistent and severe infections despite treatment with prophylactic antibiotics?
    ❑ Yes ❑ No

RE-AUTHORIZATION

12. Has the member demonstrated a clinical response to therapy such as a reduction in bacterial infections?
    ❑ Yes ❑ No ***Action Required: Please attach documentation supporting a clinical response to therapy.***

Section B: Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

NEW START

13. Does the member have significant functional disability (prior to initiating therapy)? ***Action Required: If Yes, please attach notes documenting baseline functional disability.*** ❑ Yes ❑ No

14. Was the diagnosis of CIDP confirmed by slowing of nerve conduction velocity on electromyography (EMG) or nerve conduction studies (NCS)? ***Action Required: If Yes, please attach a copy of the EMG/NCS report***
    ❑ Yes ❑ No

15. Was the diagnosis of CIDP confirmed by nerve biopsy or by elevated spinal fluid protein on lumbar puncture?
    Action Required: If Yes, please attach a copy of the laboratory report. ❑ Yes ❑ No

RE-AUTHORIZATION

16. Has the member demonstrated significant clinical improvement since starting IVIG/SCIG therapy (including improvement in sensory symptoms where applicable)? ***Action Required: If Yes, please attach documentation (ie, chart notes or medical records) that document clinical improvement.*** ❑ Yes ❑ No

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17. What is the total duration of treatment with IVIG/SCIG for CIDP? _____Months
If less than 24 months for IVIG and less than 18 months for SCIG, no further questions

18. Has SCIG/IVIG dose reduction or withdrawal of treatment been periodically attempted, and the effects measured, to validate continued use? ***Action Required: If Yes, please attach documentation that describes an attempt to reduce the dose or withdraw treatment.*** ❑ Yes ❑ No

Section C: Multifocal Motor Neuropathy (MMN)

NEW START

19. Was the diagnosis of MMN confirmed by demonstration of conduction block on electromyography (EMG) or nerve conduction studies (NCS)? ***Action Required: If Yes, please attach a copy of the EMG/NCS report.*** ❑ Yes ❑ No

20. Was the diagnosis of MMN confirmed by the presence of elevated anti-GM1 antibody titers? ***Action Required: If Yes, please attach a copy of the laboratory report.*** ❑ Yes ❑ No

21. Was conventional therapy for MMN either ineffective or not tolerated? ❑ Yes ❑ No

RE-AUTHORIZATION

22. Has the member experienced improvement in disability and maintenance of improvement with IVIG therapy? ❑ Yes ❑ No

Section D: Guillain-Barre Syndrome

23. Is plasma exchange not available or not an appropriate treatment option? ❑ Yes ❑ No

24. Which of the following clinical features of GBS does the member have? ***Action Required: Please attach documentation of pulmonary function testing and/or clinical notes that document functional status and course of illness***. *Indicate any/all that apply:*
❑ Deteriorating pulmonary function tests
❑ Rapid deterioration with symptoms for less than 2 weeks
❑ Rapid deterioration of ability to ambulate
❑ Frank inability to ambulate independently for 10 meters
❑ Other/none of the above

Section E: Dermatomyositis

NEW START

25. Did the member's condition fail to respond to first-line treatment with corticosteroids? ❑ Yes ❑ No

RE-AUTHORIZATION

26. Has the member experienced improvement in disability and maintenance of improvement with IVIG therapy? ❑ Yes ❑ No

Section F: Myasthenia Gravis *Complete for both New Start and Re-authorization*

27. Is IVIG prescribed for a member experiencing a myasthenic crisis (ie, acute episode of respiratory muscle weakness)? ❑ Yes ❑ No *If No, skip to #29*

28. Is plasma exchange not available or is not an appropriate treatment option? ❑ Yes ❑ No *No further questions*

29. Is IVIG prescribed for a member with chronic debilitating myasthenia gravis? ❑ Yes ❑ No

30. Has the member experienced an inadequate response or toxicity from treatment with cholinesterase inhibitors, corticosteroids, and/or azathioprine? ❑ Yes ❑ No

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RE-AUTHORIZATION

31. Has the member experienced improvement in disability and maintenance of improvement with IVIG therapy?
    ❑ Yes ❑ No

Section G: Autoimmune Mucocutaneous Blistering Diseases

32. Does the member have severe progressive disease despite treatment with conventional therapy (eg, corticosteroid, azathioprine, or cyclophosphamide)? ❑ Yes ❑ No

Section H: Kawasaki Syndrome

33. Will IVIG be used in conjunction with aspirin? ❑ Yes ❑ No

Section I: Bone Marrow/Hematopoietic Stem Cell Transplant Recipient

34. Is IVIG prescribed to prevent graft-versus-host disease after allogeneic bone marrow/hematopoietic stem cell transplantation (BMT/HSCT)? *If Yes, skip to # 36* ❑ Yes ❑ No

35. Is IVIG prescribed for prevention of infection after BMT/HSCT? ❑ Yes ❑ No

36. What was the date of the BMT/HSCT? _____/_____/_____
    MM DD YY

Section J: Pediatric HIV Infection

37. Is IVIG prescribed to prevent infections associated with HIV infection? ❑ Yes ❑ No

38. Is this request for a new start or continuation of IVIG therapy?
    If New start, no further questions ❑ New start ❑ Continuation

39. Has the member demonstrated a clinical response to therapy such as a reduction in bacterial infections?
    ❑ Yes ❑ No

Section K: Chronic Lymphocytic Leukemia (CLL)

40. Is IVIG prescribed to prevent infections associated with CLL? ❑ Yes ❑ No *If Continuation, skip to #44*

41. Does/did the member have hypogammaglobulinemia prior to initiating IVIG therapy? ❑ Yes ❑ No

42. Does/did the member have a history of recurrent bacterial infections prior to initiating IVIG therapy?
    ❑ Yes ❑ No *No further questions*

43. Has the member experienced a reduction in infections with IVIG therapy? ❑ Yes ❑ No *No further questions*

44. Has the member demonstrated a clinical response to therapy such as a reduction in bacterial infections?
    ❑ 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)**

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