SCIG – Hizentra, HyQvia, Cutaquig, Cuvitru, Xembify

CareFirst 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 1-855-330-1720**. 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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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*

Indicate the requested drug:
❑ Hizentra ❑ HyQvia ❑ Cutaquig ❑ Cuvitru ❑ Xembify ❑ Other _____

What is the ICD-10 code? _____

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

 SCIG 2043-A SGM SOC 5392-A – 08/2024.

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Site of Service Questions:

A. Where will this drug be administered?
- ❑ Ambulatory surgical, *skip to Clinical Criteria Questions*
- ❑ Home infusion, *skip to Clinical Criteria Questions*
- ❑ Off-campus Outpatient Hospital, *Continue to B*
- ❑ On-campus Outpatient Hospital, *Continue to B*
- ❑ Physician office, *skip to Clinical Criteria Questions*
- ❑ Pharmacy, *skip to Clinical Criteria Questions*

B. Is the patient less than 14 years of age?
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to C*

C. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes - This is a continuation of an existing treatment., *Continue to D*
- ❑ No - This is a new therapy request (patient has not received requested medication in the last 6 months)*,* ***ACTION REQUIRED: Please attach supporting clinical documentation.*** *skip to Clinical Criteria Questions*
- ❑ No - This is a request for a different brand of subcutaneous Ig product that the patient has not received previously*,* ***ACTION REQUIRED: Please attach supporting clinical documentation.*** *skip to Clinical Criteria Questions*

D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to E*

E. Does the patient have laboratory confirmed anti-IgA antibodies? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to F*

F. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation.
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to G*

G. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to H*

H. Are ***all*** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? ***ACTION REQUIRED: If Yes, please attach supporting documentation.***
- ❑ Yes, *continue to Clinical Criteria Questions*
- ❑ No, *continue to Clinical Criteria Questions*

Clinical Criteria Questions:

1. What is the diagnosis?

❒ Primary immunodeficiency (e.g., common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency, Wiskott-Aldrich syndrome), *Continue to 2*

❒ Myasthenia gravis, *Continue to 60*

❒ Chronic inflammatory demyelinating polyneuropathy (CIDP), *Continue to 40*

❒ Immune thrombocytopenic purpura (ITP), *Continue to 66*

❒ B-cell chronic lymphocytic leukemia (CLL), *Continue to 84*

❒ Stiff-person syndrome, *Continue to 64*

❒ Bone marrow transplant/hematopoietic stem cell transplant (BMT/HSCT), *Continue to 89*

❒ Dermatomyositis, *Continue to 51*

❒ Polymyositis, *Continue to 51*

❒ Multifocal motor neuropathy, *Continue to 47*

❒ Human immunodeficiency virus (HIV) infection, *Continue to 94*

❒ Guillain-Barre syndrome, *Continue to 129*

❒ Lambert-Eaton myasthenic syndrome, *Continue to 117*

❒ Parvovirus B19-induced pure red cell aplasia, *Continue to 58*

❒ Kawasaki syndrome (pediatric), *No further questions*

❒ Fetal/neonatal alloimmune thrombocytopenia, *No further questions*

❒ Isoimmune hemolytic disease of newborn, *No further questions*

❒ Neonatal hemochromatosis, *Continue to 149*

❒ Immune checkpoint inhibitor related toxicity, *Continue to 124*

❒ CAR-T therapy related hypogammaglobulinemia, *Continue to 127*

❒ Acquired red cell aplasia, *No further questions*

❒ Acute disseminated encephalomyelitis, *Continue to 131*

❒ Rasmussen encephalitis, *Continue to 154*

❒ Enteroviral meningoencephalitis, *Continue to 144*

❒ Autoimmune mucocutaneous blistering disease (includes pemphigus vulgaris, pemphigus foliaceus, bullous Pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita), *Continue to 132*

❒ Autoimmune hemolytic anemia, *Continue to 135*

❒ Autoimmune neutropenia, *Continue to 139*

❒ Systemic lupus erythematosus, *Continue to 161*

❒ Birdshot retinochoroidopathy, *Continue to 140*

❒ BK virus associated nephropathy, *No further questions*

❒ Churg-Strauss syndrome, *Continue to 141*

❒ Hematophagocytic lymphohistiocytosis (HLH), *Continue to 145*

❒ Macrophage Activation Syndrome (MAS), *Continue to 145*

❒ Hyperimmunoglobulinemia E syndrome, *Continue to 147*

❒ Multiple myeloma, *Continue to 148*

❒ Opsoclonus-myoclonus, *Continue to 151*

❒ Post-transfusion purpura, *No further questions*

❒ Solid organ transplantation, *Continue to 156*

❒ Major surgery associated secondary immunosuppression, *Continue to 158*

❒ Hematologic malignancy associated secondary immunosuppression, *Continue to 158*

❒ Major burns associated secondary immunosuppression, *Continue to 158*

❒ Collagen-vascular disease associated secondary immunosuppression, *Continue to 158*

❒ Toxic epidermal necrolysis, *Continue to 160*

❒ Stevens-Johnson syndrome, *Continue to 160*

❒ Toxic shock syndrome, *Continue to 164*

❒ Toxic necrotizing fasciitis, *Continue to 163*

❒ Measles (Rubeola) prophylaxis, *Continue to 168*

❒ Tetanus treatment and prophylaxis, *Continue to 170*

❒ Varicella prophylaxis, *Continue to 171*

❒ Other, please specify. _____app, *No further questions*

2. Is this request for continuation of immune globulin therapy?
❒ Yes, *Continue to 36*
❒ No, *Continue to 3*

3. What is the specific immunodeficiency disorder?

❒ Common variable immunodeficiency (CVID), *Continue to 17*

❒ Hypogammaglobulinemia (unspecified) or other predominant antibody deficiency disorder, *Continue to 21*

❒ IgG subclass deficiency, *Continue to 27*

❒ Selective IgA deficiency, *Continue to 23*

❒ Selective IgM deficiency, *Continue to 25*
❒ Severe combined immunodeficiency (SCID). Please provide specific diagnosis: _____, *Continue to 4*
❒ Other non-SCID combined immunodeficiency disorder. Please specify. _____, *Continue to 15*

❒ Congenital agammaglobulinemia (e.g., X-linked or autosomal recessive agammaglobulinemia), *Continue to 11*

❒ Specific antibody deficiency, *Continue to 30*
❒ Other immunodeficiency disorder/none of the above. Please specify. _____, *No further questions*

4. Was the diagnosis confirmed by molecular or genetic testing? ***ACTION REQUIRED***: If Yes, attach a copy of the laboratory report or other medical record that shows the results of molecular/genetic testing. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 5*
❒ No, *Continue to 6*

5. Is a copy of the laboratory report or other medical record with results of molecular/genetic testing attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

6. What is the patient's pre-treatment IgG level? _____ ***ACTION REQUIRED***: Attach a copy of the laboratory report with the pre-treatment IgG level.

❒ Less than 200 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 7*

❒ Greater than or equal to 200 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 8*

7. Is a copy of the laboratory report with the pretreatment IgG level attached?

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

8. Are maternal T cells present in the circulation?
❒ Yes, *No Further Questions*
❒ No, *Continue to 9*

9. What is the patient's CD3 T-cell count? ***ACTION REQUIRED***: Attach a copy of the laboratory report with lymphocyte subset enumeration by flow cytometry.

❒ Less than 300/microliter ***ACTION REQUIRED****: Submit supporting documentation, Continue to 10*
❒ Greater than or equal to 300/microliter ***ACTION REQUIRED****: Submit supporting documentation, Continue to 10*

10. Is a copy of the laboratory report with CD3 T-cell count attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

11. Was the diagnosis confirmed by molecular or genetic testing? ***ACTION REQUIRED***: If Yes, attach a copy of the laboratory report or other medical record that shows the results of molecular/genetic testing. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 12*
❒ No, *Continue to 13*

12. Is a copy of the laboratory report or other medical record with results of molecular/genetic testing attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

13. What is the patient's pre-treatment IgG level? ***ACTION REQUIRED***: If IgG is less than 200 mg/dL, attach a copy of the laboratory report with the pre-treatment IgG level.

_____ mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 14*

14. Is a copy of the laboratory report with the pretreatment IgG level attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

15. Was the diagnosis confirmed by molecular or genetic testing? ***ACTION REQUIRED***: If Yes, attach a copy of the laboratory report or other medical record that shows the results of molecular/genetic testing.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 16*

❒ No, *Continue to 31*

❒ Not applicable to diagnosis, *Continue to 31*

16. Is a copy of the laboratory report or other medical record with results of molecular/genetic testing attached?
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

17. What is the patient's age? _____

❒ Less than 2 years, *Continue to 18*

❒ Greater than or equal to 2 years, *Continue to 18*

18. Have other causes of immune deficiency been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy)?

❒ Yes, *Continue to 19*
❒ No, *Continue to 19*

19. What is the patient's pre-treatment IgG level? _____ ***ACTION REQUIRED***: Attach a copy of the laboratory report with the pre-treatment IgG level.

❒ Less than 500 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 31*

❒ Greater than or equal to 500 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 20*

20. Is the patient's pretreatment IgG level greater than or equal to 2 SD below the mean for age?
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

21. What is the patient's pre-treatment IgG level? _____***ACTION REQUIRED***: Attach a copy of the laboratory report with the pre-treatment IgG level.

❒ Less than 500 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 31*

❒ Greater than or equal to 500 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 22*

22. Is the patient's pretreatment IgG level greater than or equal to 2 SD below the mean for age?
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

23. What is the patient's pre-treatment IgA level? _____ ***ACTION REQUIRED***: Attach a copy of the laboratory report with the pre-treatment IgA level.

❒ Less than 7 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 24*

❒ Greater than or equal to 7 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 31*

24. Does the patient have normal pre-treatment IgG and IgM levels?
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

25. What is the patient's pre-treatment IgM level? ***ACTION REQUIRED***: If IgM is less than 30 mg/dL, attach a copy of the laboratory report with the pre-treatment IgM level.

_____mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 26*

26. Does the patient have normal pre-treatment IgG and IgA levels?
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

27. Does the patient have low levels of any of the following IgG subclasses? ***ACTION REQUIRED***: If Yes, attach a copy of the laboratory report with the pre-treatment IgG subclass level(s).

❒ IgG1 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 28*

❒ IgG2 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 28*

❒ IgG3 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 28*

❒ Other, please specify. _____, *Continue to 28*

28. Was the IgG subclass level greater than or equal to 2 SD below the mean for age measured on at least 2 different occasions?
❒ Yes, *Continue to 29*
❒ No, *Continue to 29*

29. Does the patient have normal pre-treatment total IgG levels, normal IgM levels and normal/low IgA levels?

❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

30. Does the patient have normal pre-treatment IgG, IgA, and IgM levels? ***ACTION REQUIRED***: If Yes, attach a copy of the laboratory report with the pre-treatment IgG, IgM, and IgA levels. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

31. Does the patient have a history of recurrent bacterial infections (e.g., pneumonia, otitis media, sinusitis, sepsis, gastrointestinal infections)?
❒ Yes, *Continue to 32*
❒ No, *Continue to 32*

32. Was the immune globulin therapy initiated in the hospital setting?
❒ Yes, *Continue to 35*
❒ No, *Continue to 33*

33. What is the patient's age? _____

❒ Less than 2 years of age, *Continue to 35*

❒ 2 years of age or older, *Continue to 34*
34. Has the patient demonstrated an impaired antibody response to vaccination with a pneumococcal polysaccharide vaccine? ***ACTION REQUIRED***: If Yes, attach a copy of the laboratory report with post-vaccination titers. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 35*
❒ No, *Continue to 35*

35. Has all required documentation been attached?

❒ Yes, *No further questions*

❒ No, *No further questions*

❒ Not applicable, *No further questions*

36. Has the patient experienced a reduction in the frequency of bacterial infections since starting immune globulin therapy?
❒ Yes, *Continue to 37*
❒ No, *Continue to 37*

37. Does the prescriber measure trough IgG levels at least once per year?

❒ Yes, *Continue to 38*

❒ No, *Continue to 38*

❒ Not applicable for diagnosis, *No further questions*

38. Is the most recent trough IgG level at or above the lower range of normal for age? ***ACTION REQUIRED***: If Yes, attach a copy of the laboratory report with a recent IgG trough level.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *Continue to 39*

❒ Not applicable for diagnosis, *No further questions*

39. Will the prescriber re-evaluate the dose of immune globulin and consider a dose adjustment (when clinically appropriate)?

❒ Yes, *No further questions*

❒ No, *No further questions*

❒ Not applicable/not clinically appropriate, *No further questions*

40. Is this request for continuation of immune globulin therapy?
❒ Yes, *Continue to 45*
❒ No, *Continue to 41*

41. Is the disease course progressive or relapsing/remitting for 2 months or longer?
❒ Yes, *Continue to 42*
❒ No, *Continue to 42*

42. Does the patient have moderate to severe functional disability?
❒ Yes, *Continue to 43*
❒ No, *Continue to 43*

43. 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. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 44*
❒ No, *Continue to 44*

44. Are the electrodiagnostic study results attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

45. Has the patient demonstrated significant improvement in disability and maintenance of improvement since starting IG therapy?
❒ Yes, *Continue to 46*
❒ No, *Continue to 46*

46. Is IG being used at the lowest effective dose and frequency?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

47. Is this request for continuation of immune globulin therapy?
❒ Yes, *Continue to 56*
❒ No, *Continue to 48*

48. Has the patient experienced progressive, multifocal, asymmetrical weakness without objective sensory loss in 2 or more nerves for at least 1 month?
❒ Yes, *Continue to 49*
❒ No, *Continue to 49*

49. 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. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 50*
❒ No, *Continue to 50*

50. Are the electrodiagnostic study results attached?

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

51. Is this request for continuation of immune globulin therapy?
❒ Yes, *Continue to 57*
❒ No, *Continue to 52*

52. Does the patient exhibit at least 4 of the following clinical features: a) Proximal muscle weakness (upper or lower extremity and trunk), b) Elevated serum creatine kinase (CK) or aldolase level, c) Muscle pain on grasping or spontaneous pain, d) Myogenic changes on EMG (short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials), e) Positive for anti-synthetase antibodies (e.g., anti-Jo-1, also called histadyl tRNA synthetase), f) Non-destructive arthritis or arthralgias, g) Systemic inflammatory signs (fever: more than 37 degrees Celsius at axilla, elevated serum CRP level or accelerated ESR of more than 20 mm/h by the Westergren method, h) Pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen)?
❒ Yes, *Continue to 53*
❒ No, *Continue to 53*

53. Were standard first line (corticosteroids) and second line (immunosuppressants) treatments tried but were unsuccessful or not tolerated? ***ACTION REQUIRED***: If Yes, attach supporting chart note(s) describing previous standard treatments tried and failed. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 55*
❒ No, *Continue to 54*

54. Is the patient unable to receive standard first-line and second-line therapy because of a contraindication or other clinical reason? ***ACTION REQUIRED***: If Yes, attach supporting chart note(s) describing previous standard treatments tried and failed. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 55*
❒ No, *Continue to 55*

55. Is all required documentation attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

56. Has the patient demonstrated significant improvement in disability and/or maintenance of improvement since starting IG therapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

57. Has the patient demonstrated significant improvement in disability and/or maintenance of improvement since starting IG therapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

58. Does the patient have severe, refractory anemia associated with bone marrow suppression?
❒ Yes, *Continue to 59*
❒ No, *Continue to 59*

59. Does the patient have parvovirus B19 viremia? ***ACTION REQUIRED***: If Yes, attach test result confirming presence of parvovirus B19. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

60. What is the primary reason IG is being prescribed?

❒ Refractory myasthenia gravis, *Continue to 63*

❒ Acute exacerbation/crisis, *Continue to 61*

❒ Worsening weakness, *Continue to 62*

❒ Pre-operative management (e.g., prior to thymectomy), *No further questions*

❒ Other, please specify. _____, *No further questions*

61. Does the patient have severe swallowing difficulty and/or respiratory failure?
❒ Yes, *No Further Questions*
❒ No, *Continue to 62*

62. 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 Further Questions*
❒ No, *No Further Questions*

63. Has the patient tried and failed 2 or more standard therapies (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab)? ***ACTION REQUIRED***: If Yes, attach supporting chart note(s) describing standard treatments tried and failed. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

64. Has the diagnosis been confirmed by anti-glutamic acid decarboxylase (GAD) antibody testing? ***ACTION REQUIRED***: If Yes, attach GAD antibody test results. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 65*
❒ No, *Continue to 65*

65. Has the patient received first-line treatment with benzodiazepines and/or baclofen and experienced an inadequate response? ***ACTION REQUIRED***: If Yes, attach supporting chart note(s) describing previous standard treatments tried and failed. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

66. Is the patient a pregnant woman? If Yes, please provide estimated date of delivery.
❒ Yes, please indicate estimated date of delivery: _____ MM/DD/YY, *No further questions*

❒ No, *Continue to 67*

67. Is the patient an adult with refractory ITP after splenectomy?
❒ Yes, *Continue to 68*
❒ No, *Continue to 70*

68. What is the current pre-treatment platelet count? ***ACTION REQUIRED***: Attach lab report with platelet count.
❒ Less than 30,000/mcL (30 x 10 9/L) ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Greater than or equal to 30,000/mcL (30 x 10 9/L) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 69*

69. Does the patient have significant bleeding symptoms (e.g., mucosal bleeding or other moderate to severe bleeding)?

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

70. What is the classification of ITP?

❒ Newly-diagnosed ITP (diagnosed within the past 3 months), *Continue to 71*

❒ Previously untreated ITP (initial therapy), *Continue to 71*

❒ Chronic or persistent ITP (greater than or equal to 3 months from diagnosis), *Continue to 79*

❒ ITP unresponsive to first-line treatment, *Continue to 79*

❒ Other, please specify. _____, *No further questions*

71. What is the patient's age? _____

❒ Less than 18 years of age, *Continue to 72*

❒ 18 years of age or older, *Continue to 74*

72. Does the patient have significant bleeding symptoms (e.g., mucosal bleeding or other moderate to severe bleeding)?
❒ Yes, *No Further Questions*
❒ No, *Continue to 73*

73. Is the patient at high risk for bleeding or does the patient require a rapid increase in platelets? If Yes, please indicate the risk factors for bleeding or reason for a rapid increase in platelets.

❒ Yes, undergoing a medical or dental procedure where blood loss is anticipated, *No further questions*

❒ Yes, comorbidity (e.g., peptic ulcer disease or hypertension), *No further questions*

❒ Yes, mandated anticoagulation therapy, *No further questions*
❒ Yes, profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete), *No further questions*

❒ Other, please specify. _____, *No further questions*

❒ No, not at high risk or does not require rapid increase in platelets, *No further questions*

4. What is the current pre-treatment platelet count? ***ACTION REQUIRED***: Attach lab report with platelet count.

❒ Less than 30,000/mcL (30 x 10 9/L) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 77*
❒ 30,000 to less than 50,000/mcL (30 x 10 9/L to < 50 x 10 9/L) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 75*
❒ Greater than or equal to 50,000/mcl (50 x 10 9/L) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 75*

75. Does the patient have significant bleeding symptoms (e.g., mucosal bleeding or other moderate to severe bleeding)?
❒ Yes, *Continue to 77*
❒ No, *Continue to 76*

76. Is the patient at high risk for bleeding or does the patient require a rapid increase in platelets? If Yes, please indicate the risk factors for bleeding or reason for a rapid increase in platelets.

❒ Yes, Undergoing a medical or dental procedure where blood loss is anticipated, *Continue to 77*

❒ Yes, comorbidity (e.g., peptic ulcer disease or hypertension), *Continue to 77*

❒ Yes, mandated anticoagulation therapy, *Continue to 77*
❒ Yes, profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete), *Continue to 77*

❒ Other, please specify. _____, *No further questions*

❒ No, not at high risk or does not require rapid increase in platelets, *No further questions*

77. Please indicate the prescribed regimen.

❒ IG monotherapy, *Continue to 78*

❒ IG in combination with corticosteroid, *No further questions*

❒ Other, please specify. _____, *No further questions*

78. Is corticosteroid therapy contraindicated?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

79. What is the current pre-treatment platelet count? ***ACTION REQUIRED***: Attach lab report with platelet count.

❒ Less than 30,000/mcL (30 x 10 9/L) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 82*
❒ 30,000 to less than 50,000/mcL (30 x 10 9/L to < 50 x 10 9/L) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 80*
❒ Greater than or equal to 50,000/mcL (50 x 10 9/L) ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

80. Does the patient have significant bleeding symptoms (e.g., mucosal bleeding or other moderate to severe bleeding)?
❒ Yes, *Continue to 82*
❒ No, *Continue to 81*

81. Is the patient at high risk for bleeding or does the patient require a rapid increase in platelets? If Yes, please indicate the risk factors for bleeding or reason for a rapid increase in platelets.

❒ Yes, undergoing a medical or dental procedure where blood loss is anticipated, *Continue to 82*

❒ Yes, comorbidity (e.g., peptic ulcer disease or hypertension), *Continue to 82*

❒ Yes, mandated anticoagulation therapy, *Continue to 82*
❒ Yes, profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete), *Continue to 82*

❒ Other, please specify. _____, *Continue to 82*

❒ No, not at high risk or does not require rapid increase in platelets, *Continue to 82*

82. Does the patient have relapsed ITP after a previous response to IG therapy?
❒ Yes, *No Further Questions*
❒ No, *Continue to 83*

83. Does the patient have a history of inadequate response, intolerance or a contraindication to corticosteroid or anti-D therapy? ***ACTION REQUIRED***: If Yes, attach supporting chart note(s) describing previous treatments or contraindication. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

84. Is this request for continuation of immune globulin therapy?
❒ Yes, *Continue to 116*
❒ No, *Continue to 85*

85. Is IG prescribed for prophylaxis of bacterial infections?
❒ Yes, *Continue to 86*
❒ No, *Continue to 86*

86. Does the patient have a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization?
❒ Yes, *Continue to 87*
❒ No, *Continue to 87*

87. What is the patient's pre-treatment IgG level? ***ACTION REQUIRED***: If IgG is less than 500 mg/dL, attach a copy of the laboratory report with the pre-treatment IgG level.

_____mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 88*

88. Is a copy of the laboratory report with the pretreatment IgG level attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

89. Is this request for continuation of immune globulin therapy?
❒ Yes, *Continue to 116*
❒ No, *Continue to 90*

90. Will therapy be used to prevent the risk of acute graft-versus-host disease, associated interstitial pneumonia (infectious or idiopathic), septicemia and other infections (e.g., cytomegalovirus infections [CMV], recurrent bacterial infections)?
❒ Yes, *Continue to 91*
❒ No, *Continue to 91*

91. Has the patient received a bone marrow/hematopoietic stem cell transplant within the past 100 days?
❒ Yes, *No Further Questions*
❒ No, *Continue to 92*

92. What is the patient's pre-treatment IgG level (mg/dL)? ***ACTION REQUIRED***: If IgG is less than 400 mg/dL, attach a copy of the laboratory report with the pre-treatment IgG level.

_____mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 93*

93. Is a copy of the laboratory report with the pretreatment IgG level attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

94. Is the requested drug being prescribed for prophylaxis of bacterial infections in a pediatric patient?
❒ Yes, *Continue to 107*
❒ No, *Continue to 95*

95. Is the requested drug being prescribed for treatment of thrombocytopenia associated with HIV?
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

96. Is the patient an adult?
❒ Yes, *Continue to 97*
❒ No, *Continue to 101*

97. Does the patient have significant bleeding?
❒ Yes, *Continue to 98*
❒ No, *Continue to 98*

98. What is the patient's platelet count (mcL)?

_____mcL, *Continue to 99*

99. Is the patient Rh-positive?
❒ Yes, *Continue to 100*
❒ No, *No Further Questions*

100. Has the patient failed treatment with RhIG?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

101. What is the patient's pre-treatment IgG level? ***ACTION REQUIRED***: If IgG is less than 400 mg/dL, attach a copy of the laboratory report with the pre-treatment IgG level.

_____mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 102*

102. Has the patient had 2 or more bacterial infections in a 1-year period despite antibiotic chemoprophylaxis with TMP-SMZ or another active agent?
❒ Yes, *No Further Questions*
❒ No, *Continue to 103*

103. Has the patient received 2 doses of measles vaccine and lives in a region with a high prevalance of measles?
❒ Yes, *No Further Questions*
❒ No, *Continue to 104*

104. Does the patient have HIV-associated thrombocytopenia despite anti-retroviral therapy?
❒ Yes, *No Further Questions*
❒ No, *Continue to 105*

105. Does the patient have chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy?
❒ Yes, *No Further Questions*
❒ No, *Continue to 106*

106. What is the patient's T4 cell count (mm3)?

_____/mm3, *No further questions*

107. Is this request for continuation of immune globulin therapy?
❒ Yes, *Continue to 116*
❒ No, *Continue to 108*

108. Please indicate whether IG will be used for primary or secondary prophylaxis.

❒ Primary prophylaxis, *Continue to 109*

❒ Secondary prophylaxis, *Continue to 110*

❒ Other, please specify. _____, *Continue to 111*

109. What is the patient's pre-treatment IgG level? _____ ***ACTION REQUIRED***: If IgG is less than 400 mg/dL, attach a copy of the laboratory report with the pre-treatment IgG level.

❒ Less than 400 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ Greater than or equal to 400 mg/dL, *Continue to 111*

110. Does the patient have a history of recurrent bacterial infections (>2 serious bacterial infections in a 1-year period)?

❒ Yes, *No Further Questions*
❒ No, *Continue to 111*

111. Has the patient failed to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine?
❒ Yes, *No Further Questions*
❒ No, *Continue to 112*

112. Is this request for a single dose of immune globulin for a patient who has been exposed to measles?
❒ Yes, *No Further Questions*
❒ No, *Continue to 113*

113. Does the patient live in an area where measles is highly prevalent?
❒ Yes, *Continue to 114*
❒ No, *Continue to 115*

114. Has the patient failed to develop an antibody response after two doses of measles, mumps, and rubella live virus vaccine?
❒ Yes, *No Further Questions*
❒ No, *Continue to 115*

115. Does the patient have chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

116. Has the patient experienced a reduction in the frequency of bacterial infections since starting IG therapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

117. Is this request for continuation of immune globulin therapy?
❒ Yes, *Continue to 123*
❒ No, *Continue to 118*

118. 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, attach a copy of the laboratory report, neurophysiology study report or other supporting medical record(s).

❒ Yes, neurophysiology studies ***ACTION REQUIRED****: Submit supporting documentation, Continue to 119*
❒ Yes, positive anti- P/Q type voltage-gated calcium channel antibody test ***ACTION REQUIRED****: Submit supporting documentation, Continue to 119*

❒ No, *Continue to 119*

119. Has the patient tried an anticholinesterase (e.g., pyridostigmine) but it was unsuccessful or not tolerated?
❒ Yes, *Continue to 120*
❒ No, *Continue to 120*

120. Has the patient tried amifampridine (e.g., 3,4-diaminopyridine phosphate, Firdapse) but it was unsuccessful or not tolerated?
❒ Yes, *Continue to 121*
❒ No, *Continue to 121*

121. Does the patient have severe weakness?

❒ Yes, *No Further Questions*
❒ No, *Continue to 122*

122. Is there difficulty with venous access for plasmapheresis?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

123. Has the patient experienced stability or improvement in symptoms relative to the natural course of LEMS?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

124. 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, *Continue to 125*
❒ No, *Continue to 125*

125. Is the offending drug being temporarily held or has it been discontinued permanently?
❒ Yes, *Continue to 126*
❒ No, *Continue to 126*

126. Which of the following adverse events did the patient experience?

❒ Pneumonitis, *No further questions*

❒ Myasthenia gravis, *No further questions*

❒ Peripheral neuropathy, *No further questions*

❒ Encephalitis, *No further questions*

❒ Transverse myelitis, *No further questions*

❒ Severe inflammatory arthritis, *No further questions*

❒ Myocarditis, *No further questions*

❒ Bullous dermatitis, *No further questions*

❒ Stevens-Johnson syndrome, toxic epidermal necrolysis, *No further questions*

❒ Guillain-Barre syndrome, *No further questions*

❒ Steroid-refractory myalgias or myositis, *No further questions*

❒ Other, please specify. _____, *No further questions*

127. Has the patient received treatment with CAR-T therapy (including but not limited to: idecabtagene vicleucel [Abecma],tisagenlecleucel [Kymriah] or axicabtagene ciloleucel [Yescarta]?
❒ Yes, *Continue to 128*
❒ No, *Continue to 128*

128. What is the patient's IgG level (mg/dL)? ***ACTION REQUIRED***: If IgG is less than 400 mg/dL, attach a copy of the laboratory report with the pre-treatment IgG level.

_____mg/dL ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

129. Does the patient have severe disease with significant weakness (e.g., inability to stand or walk without aid, respiratory weakness)?
❒ Yes, *Continue to 130*
❒ No, *Continue to 130*

130. Did the onset of neurologic symptoms occur less than 4 weeks from the anticipated start of immunoglobulin therapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

131. Has the patient had an insufficient response or contraindication to intravenous corticosteroid treatment?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

132. Has the diagnosis been proven by biopsy and confirmed by pathology report?
❒ Yes, *Continue to 133*
❒ No, *Continue to 133*

133. Is the condition rapidly progressing, extensive, or debilitating?
❒ Yes, *Continue to 134*
❒ No, *Continue to 134*

134. Has the patient failed or experienced significant complications (e.g., diabetes, steroid-induced osteoporosis) from standard treatment (corticosteroids, immunosuppressive agents)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

135. Which type of autoimmune hemolytic anemia does the patient have?

❒ Warm type, *Continue to 136*

❒ Cold type, *Continue to 136*

❒ Other, please specify. _____, *Continue to 136*

136. Has the patient tried corticosteroids with inadequate response?
❒ Yes, *No Further Questions*
❒ No, *Continue to 137*

137. Has the patient had a splenectomy with inadequate response?
❒ Yes, *No Further Questions*
❒ No, *Continue to 138*

138. Does the patient have a contraindication to corticosteroids or splenectomy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

139. *No Further Questions*
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

140. Has the patient tried immunosuppressant therapy (e.g., corticosteroids, cyclosporine) with inadequate response?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

141. Does the patient have severe, active disease?
❒ Yes, *Continue to 142*
❒ No, *Continue to 142*

142. Will immune globulin be used as adjunctive therapy?
❒ Yes, *Continue to 143*
❒ No, *Continue to 143*

143. Has the patient experienced failure, intolerance, or is contraindicated to other interventions?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

144. Is the patient's condition severe?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

145. What is the patient's total IgG level (mg/dL)? _____***ACTION REQUIRED***: Attach a copy of the laboratory report with the pre-treatment IgG level.

❒ Less than 400 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ 400 mg/dL or greater ***ACTION REQUIRED****: Submit supporting documentation, Continue to 146*

146. Is the total IgG level at least two standard deviations below the mean for age?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

147. Does the patient have severe eczema?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

148. Does the patient have recurrent, serious infections despite the use of prophylactic antibiotics?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

149. Is the patient currently pregnant?
❒ Yes, *Continue to 150*
❒ No, *Continue to 150*

150. Does the patient have a history of pregnancy ending in documented neonatal hemochromatosis?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

151. Does the patient have paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma?
❒ Yes, *No Further Questions*
❒ No, *Continue to 152*

152. Does the patient have refractory opsoclonus-myoclonus?
❒ Yes, *Continue to 153*
❒ No, *Continue to 153*

153. Is immune globulin being used as last-resort treatment?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

154. Did the patient try anti-epileptic drugs with no improvement in symptoms?

❒ Yes, *Continue to 155*
❒ No, *Continue to 155*

155. Did the patient try corticosteroids with no improvement in symptoms?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

156. Is immune globulin being prescribed for solid organ transplantation in an allosensitized patient?
❒ Yes, *No Further Questions*
❒ No, *Continue to 157*

157. Is the patient undergoing renal transplantation from a live donor with ABO incompatibility or positive cross match?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

158. Is immune globulin being requested to prevent or modify recurrent bacterial or viral infections?
❒ Yes, *Continue to 159*
❒ No, *Continue to 159*

159. What is the patient's pre-treatment IgG level (mg/dL)? ***ACTION REQUIRED***: If IgG is less than 400 mg/dL, attach a copy of the laboratory report with the pre-treatment IgG level.

_____mg/dL ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

160. Is the patient's case severe?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

161. Does the patient have severe, active disease?
❒ Yes, *Continue to 162*
❒ No, *Continue to 162*

162. Has the patient experienced inadequate response, intolerance, or have a contraindication to first line and second line therapy (e.g., hydroxychloroquine, glucocorticoids, anifrolumab, rituximab)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

163. Does the patient have toxic necrotizing fasciitis due to invasive group A streptococcal infection? ***ACTION REQUIRED***: If Yes, attach documentation confirming presence of fasciitis (toxic necrotizing fasciitis due to group A streptococous only) and culture or Gram stain. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

164. Does the patient have toxic shock syndrome due to a staphylococcal or streptococcal infection? ***ACTION REQUIRED***: If Yes, attach culture or Gram stain. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 165*
❒ No, *Continue to 165*

165. Is the infection refractory to several hours of aggressive therapy?
❒ Yes, *No Further Questions*
❒ No, *Continue to 166*

166. Does the patient have an undrainable focus of infection?
❒ Yes, *No Further Questions*
❒ No, *Continue to 167*

167. Does the patient have persistent oliguria with pulmonary edema?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

168. Is the patient susceptible and exposed to measles less than 6 days prior to this request?
❒ Yes, *Continue to 169*
❒ No, *Continue to 169*

169. Is this request for postexposure to prevent or modify symptoms of measles (rubeola)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

170. Is this request for treatment or postexposure prophylaxis of tetanus as an alternative when tetanus immune globulin (TIG) is unavailable?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

171. Is this request for treatment or postexposure prophylaxis of varicella in susceptible patients when varicella-zoster immune globulin (VZIG) is unavailable?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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)**