



## Xembify

### 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.

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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

**Site of Service Questions:**

- A. Where will this drug be administered?
- |   |   |
|---|---|
| <input type="checkbox"/> Ambulatory surgical, <i>skip to Clinical Questions</i> | <input type="checkbox"/> Home infusion, <i>skip to Clinical Questions</i> |
| <input type="checkbox"/> Off-campus Outpatient Hospital                         | <input type="checkbox"/> On-campus Outpatient Hospital                    |
| <input type="checkbox"/> Physician office, <i>skip to Clinical Questions</i>    | <input type="checkbox"/> Pharmacy, <i>skip to Clinical Questions</i>      |
- B. Is the patient less than 21 years old or 65 years of age or older?
- Yes – less than 21 years old, *skip to Clinical Criteria Questions*
- Yes – age 65 years or older, *skip to Clinical Criteria Questions*
- No
- C. Is this request to continue previously established treatment with the requested medication?
- Yes - This is a continuation of an existing treatment.
- No - This is a new therapy request (patient has not received requested medication in the last 6 months). *skip to Clinical Criteria Questions*

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- D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids or other pre- medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? **ACTION REQUIRED: Attach supporting clinical documentation.**  
 Yes, skip to Clinical Criteria Questions  No
- E. Does the patient have laboratory confirmed anti-IgA antibodies? **ACTION REQUIRED: Attach supporting clinical documentation.**  Yes, skip to Clinical Criteria Questions  No
- 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: Attach supporting clinical documentation.**  Yes, skip to Clinical Criteria Questions  No
- 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: Attach supporting clinical documentation.**  Yes  No

**Criteria Questions:**

1. What is the diagnosis?
- |   |   |
|---|---|
| <input type="checkbox"/> Myasthenia gravis  | <input type="checkbox"/> Macrophage Activation Syndrome (MAS)   |
| <input type="checkbox"/> Chronic inflammatory demyelinating polyneuropathy (CIDP)   | <input type="checkbox"/> Hyperimmunoglobulinemia E syndrome     |
| <input type="checkbox"/> Immune thrombocytopenic purpura (ITP)  | <input type="checkbox"/> Multiple myeloma                       |
| <input type="checkbox"/> B-cell chronic lymphocytic leukemia (CLL)  | <input type="checkbox"/> Opsoclonus-myoclonus                   |
| <input type="checkbox"/> Stiff-person syndrome  | <input type="checkbox"/> Post-transfusion purpura               |
| <input type="checkbox"/> Dermatomyositis  | <input type="checkbox"/> Solid organ transplantation            |
| <input type="checkbox"/> Polymyositis   | <input type="checkbox"/> Stevens-Johnson syndrome               |
| <input type="checkbox"/> Multifocal motor neuropathy  | <input type="checkbox"/> Toxic necrotizing fasciitis            |
| <input type="checkbox"/> Human immunodeficiency virus (HIV) infection   | <input type="checkbox"/> Toxic epidermal necrolysis             |
| <input type="checkbox"/> Guillain-Barré syndrome  | <input type="checkbox"/> Toxic shock syndrome                   |
| <input type="checkbox"/> Lambert-Eaton myasthenic syndrome  | <input type="checkbox"/> Kawasaki syndrome (pediatric)          |
| <input type="checkbox"/> Parvovirus B19-induced pure red cell aplasia   | <input type="checkbox"/> Isoimmune hemolytic disease of newborn |
| <input type="checkbox"/> Fetal/neonatal alloimmune thrombocytopenia   | <input type="checkbox"/> Neonatal hemochromatosis               |
| <input type="checkbox"/> Immune checkpoint inhibitor related toxicity   | <input type="checkbox"/> Acquired red cell aplasia              |
| <input type="checkbox"/> CAR-T therapy related hypogammaglobulinemia  | <input type="checkbox"/> Acute disseminated encephalomyelitis   |
| <input type="checkbox"/> Rasmussen encephalitis   | <input type="checkbox"/> Autoimmune neutropenia                 |
| <input type="checkbox"/> Enteroviral meningoencephalitis  | <input type="checkbox"/> Autoimmune hemolytic anemia            |
| <input type="checkbox"/> Systemic lupus erythematosus   | <input type="checkbox"/> Autoimmune neutropenia                 |
| <input type="checkbox"/> Hematophagocytic lymphohistiocytosis (HLH)   | <input type="checkbox"/> BK virus associated nephropathy        |
| <input type="checkbox"/> Major surgery associated secondary immunosuppression   | <input type="checkbox"/> Churg-Strauss syndrome                 |
| <input type="checkbox"/> Major burns associated secondary immunosuppression   | <input type="checkbox"/> Birdshot retinochoroidopathy           |
| <input type="checkbox"/> Hematologic malignancy associated secondary immunosuppression  |   |
| <input type="checkbox"/> Collagen-vascular disease associated secondary immunosuppression   |   |
| <input type="checkbox"/> Bone marrow transplant/hematopoietic stem cell transplant recipient  |   |
| <input type="checkbox"/> Autoimmune mucocutaneous blistering disease (includes pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa aquisita) |   |
| <input type="checkbox"/> Primary immunodeficiency (eg, common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency, Wiskott-Aldrich syndrome)                           |   |
| <input type="checkbox"/> Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)  |   |
| <input type="checkbox"/> Pediatric acute onset neuropsychiatric syndrome (PANS)   |   |
| <input type="checkbox"/> Other _____  |   |
2. What is the ICD-10 code? \_\_\_\_\_ *If patient's diagnosis is PANDAS or PANS, no further questions*

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

Section A: Primary Immunodeficiency

3. Is this a request for continuation of immune globulin therapy?  Yes  No *If No, skip to #8*
4. Has the patient experienced a reduction in the frequency of bacterial infections since starting immune globulin therapy?  Yes  No
5. Does the prescriber measure trough IgG levels at least once per year?  
 Yes  No  Not applicable to diagnosis *If Not applicable to diagnosis, no further questions.*
6. 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.**  
*If Yes or Not applicable, no further questions.*  Yes  No  Not applicable for diagnosis
7. 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.*
8. What is the specific immunodeficiency disorder?  
 Severe combined immunodeficiency (SCID), *specify:* \_\_\_\_\_  
 Congenital agammaglobulinemia (eg, X-linked or autosomal recessive agammaglobulinemia)  
 Other non-SCID combined immunodeficiency disorder, *specify:* \_\_\_\_\_  
 Common variable immunodeficiency (CVID)  
 Hypogammaglobulinemia (unspecified) or other predominant antibody deficiency disorder  
 Selective IgA deficiency  
 Selective IgM deficiency  
 IgG subclass deficiency  
 Specific antibody deficiency  
 Other immunodeficiency disorder/none of the above, *specify:* \_\_\_\_\_
9. **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 ( $\geq$ ) 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 ( $\geq$ ) 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; Is the IgA level within the normal reference range?  Yes  No
  - IgM level: \_\_\_\_\_ mg/dL; Is the IgM level within the normal reference range?  Yes  No
10. *If diagnosis is severe combined immunodeficiency*, are maternal T cells present in the circulation?  
*If Yes, skip to #12.*  Yes  No
11. *If diagnosis is severe combined immunodeficiency*, 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.** \_\_\_\_\_ per microliter
12. Was the diagnosis confirmed by molecular or genetic testing? **ACTION REQUIRED: Please attach a copy of the laboratory report or other medical record that shows the results of molecular/genetic testing.**  
 Yes  No  Not applicable to diagnosis
13. *If the diagnosis is common variable immunodeficiency*, have other causes of immune deficiency been excluded (eg, drugs, infectious disease, malignancy)?  Yes  No  Not applicable to diagnosis

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14. Does the patient have a history of recurrent bacterial infections (eg, pneumonia, otitis media, sinusitis, sepsis, gastrointestinal infections)?  Yes  No
15. Was the immune globulin therapy initiated in the hospital setting?  Yes  No
16. Has the patient demonstrated an impaired antibody response to vaccination with a pneumococcal polysaccharide vaccine? **ACTION REQUIRED: If Yes, please attach a copy of the laboratory report with post-vaccination titers.**  Yes  No  Not applicable

**Section B: Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

17. Is this a request for continuation of immune globulin therapy? *If Yes, skip to #21*  Yes  No
18. Is the disease course progressive or relapsing/remitting for 2 months or longer?  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]) 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 and CSF analysis.**  Yes  No *No further questions*
21. Has the patient demonstrated significant improvement in disability and maintenance of improvement since starting IG therapy?  Yes  No
22. Is IG being used at the lowest effective dose and frequency?  Yes  No

**Section C: Multifocal Motor Neuropathy (MMN)**

23. Is this a request for continuation of immune globulin therapy? *If Yes, skip to #26*  Yes  No
24. Has the patient experienced progressive, multifocal, asymmetrical weakness without objective sensory loss in 2 or more nerves for at least 1 month?  Yes  No
25. 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
26. Has the patient demonstrated significant improvement in disability and/or maintenance of improvement since starting IG therapy?  Yes  No

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

27. Is this request for continuation of immune globulin therapy? *If Yes, skip to #32*  Yes  No
28. Does the patient exhibit any of the following clinical features? *Indicate ALL that apply.*
- Proximal muscle weakness (upper or lower extremity and trunk)
  - Elevated serum creatine kinase (CK) or aldolase level
  - Muscle pain on grasping or spontaneous pain
  - Myogenic changes on EMG (short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
  - Positive for anti-synthetase antibodies (e.g., anti-Jo-1, also called histadyl tRNA synthetase)
  - Non-destructive arthritis or arthralgias
  - Systemic inflammatory signs (fever: more than 37°C at axilla, elevated serum CRP level or accelerated ESR of more than 20 mm/h by the Westergren method)
  - Pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen)
  - None of the above
29. Were electrodiagnostic studies (electromyography [EMG]) and the muscle biopsy (when available) performed to confirm the diagnosis? **ACTION REQUIRED: If 'Yes', attach a copy of the EMG test results..**  Yes  No
30. 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 treatments and no further questions.**  Yes  No

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31. 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 treatments.**  
 Yes  No *No further questions*
32. Has the patient demonstrated significant improvement in disability and/or maintenance of improvement since starting IG therapy?  Yes  No

Section E: Parvovirus B19-Induced Pure Red Cell Aplasia (PRCA)

33. Does the patient have severe, refractory anemia associated with bone marrow suppression?  Yes  No
34. Does the patient have parvovirus B19 viremia? **ACTION REQUIRED: If 'yes', attach test result confirming presence of parvovirus B19.**  Yes  No

Section F: Myasthenia Gravis

35. What is the primary reason IG is being prescribed?  
 Refractory myasthenia gravis, *skip to #38*  
 Acute exacerbation/crisis  
 Worsening weakness, *skip to #37*  
 Pre-operative management (eg, prior to thymectomy), *no further questions*  
 Other \_\_\_\_\_
36. Does the patient have severe swallowing difficulty and/or respiratory failure?  
*If Yes, no further questions.*  Yes  No
37. 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*
38. Has the patient tried and failed 2 or more standard therapies (eg, corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab)? **ACTION REQUIRED: If 'Yes', attach supporting chart note(s) describing previous treatments.**  Yes  No

Section G: Stiff-Person Syndrome

39. Has the diagnosis been confirmed by anti-glutamic acid decarboxylase (GAD) antibody testing?  
**ACTION REQUIRED: If 'Yes', attach GAD antibody test results.**  Yes  No
40. 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 treatments.**  
 Yes  No

Section H: Immune Thrombocytopenic Purpura (ITP)

41. Is the patient a pregnant woman?  Yes  No  
*If yes, please provide estimated date of delivery and no further questions: \_\_\_\_\_*
42. Is the patient an adult with refractory ITP after splenectomy?  Yes  No *If No, skip to #45*
43. What is the current pre-treatment platelet count? **ACTION REQUIRED: Attach lab report with platelet count.**  
 \_\_\_\_\_ per mL *If less than 30,000/mL, no further questions.*
44. Does the patient have significant bleeding symptoms (eg, mucosal bleeding or other moderate to severe bleeding)?  
 Yes  No *No further questions*
45. 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.*  
 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

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46. What is the current pre-treatment platelet count? **ACTION REQUIRED: Attach lab report with platelet count.**  
 \_\_\_\_\_ mL
47. Does the patient have significant bleeding symptoms (eg, mucosal bleeding or other moderate to severe bleeding)?  
 Yes  No
48. What is the classification of ITP?  
 Newly-diagnosed ITP (diagnosed within the past 3 months), *no further questions if patient is less than 18 years*  
 Previously untreated ITP (initial therapy), *no further questions if patient is less than 18 years old*  
 Chronic or persistent ITP (greater than or equal to 3 months from diagnosis), *skip to #51*  
 ITP unresponsive to first-line treatment, *skip to #51*  
 Other \_\_\_\_\_
49. Please indicate the prescribed regimen.  
 IG monotherapy  
 IG in combination with corticosteroid, *no further questions*  
 Other \_\_\_\_\_
50. Is corticosteroid therapy contraindicated?  Yes  No *No further questions*
51. Does the patient have relapsed ITP after a previous response to IG therapy?  
*If Yes, no further questions.*  Yes  No
52. 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.**  Yes  No

**Section I: B-Cell Chronic Lymphocytic Leukemia (CLL), Bone Marrow Transplant/Hematopoietic Stem Cell Transplant Recipient**

53. Is this request for continuation of immune globulin therapy? *If Yes, skip to #58*  Yes  No
54. Is IG prescribed for prophylaxis of bacterial infections?  Yes  No
55. 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
56. *If diagnosis is B-cell chronic lymphocytic leukemia*, does the patient have a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization?  Yes  No *No further questions*
57. *If diagnosis is bone marrow transplant/hematopoietic stem cell transplant recipient*, has the patient received a bone marrow/hematopoietic stem cell transplant within the past 100 days?  Yes  No *No further questions*
58. Has the patient experienced a reduction in the frequency of bacterial infections since starting IG therapy?  
 Yes  No

**Section J: HIV Infection: Prophylaxis or Thrombocytopenia**

59. Is the requested drug being prescribed for prophylaxis of bacterial infections in a pediatric patient?  
*If Yes, skip to #70*  Yes  No
60. Is the requested drug being prescribed for treatment of thrombocytopenia associated with HIV?  Yes  No
61. Is the patient an adult?  Yes  No *If No, skip to #66*
62. Does the patient have significant bleeding?  Yes  No
63. What is the patient's platelet count? \_\_\_\_\_ / mL
64. Is the patient Rh-positive?  Yes  No *If No, no further questions.*
65. Has the patient failed treatment with RhIG?  Yes  No *No further questions*
66. 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

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67. Has the patient had 2 or more bacterial infections in a 1-year period despite antibiotic chemoprophylaxis with TMP-SMZ or another active agent? *If Yes, no further questions.*  Yes  No
68. Does the patient have HIV-associated thrombocytopenia despite anti-retroviral therapy? *If Yes, no further questions.*  Yes  No
69. What is the patient's T4 cell count? \_\_\_\_\_ / mm<sup>3</sup>  Unknown  
*If greater than or equal to 200/mm<sup>3</sup>, no further questions. If less than 200/mm<sup>3</sup> or unknown, skip to #76.*
70. Is this request for continuation of immune globulin therapy? *If Yes, skip to #79*  Yes  No
71. Please indicate whether IG will be used for primary or secondary prophylaxis.  
 Primary prophylaxis  Secondary prophylaxis, *skip to #73*  Other \_\_\_\_\_, *skip to #74*
72. 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  
*If less than 400 mg/dL, no further questions. If greater than or equal to 400 mg/dL, skip to #77*
73. Does the patient have a history of recurrent bacterial infections (greater than 2 serious bacterial infections in a 1-year period)? *If Yes, no further questions.*  Yes  No
74. Has the patient failed to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine? *If Yes, no further questions.*  Yes  No
75. Is this request for a single dose of immune globulin for a patient who has been exposed to measles? *If Yes, no further questions.*  Yes  No
76. Does the patient live in an area where measles is highly prevalent?  Yes  No *If No, skip to #78*
77. Has the patient failed to develop an antibody response after two doses of measles, mumps, and rubella live virus vaccine? *If Yes, no further questions.*  Yes  No
78. Does the patient have chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy?  Yes  No *No further questions*
79. Has the patient experienced a reduction in the frequency of bacterial infections since starting IG therapy?  Yes  No

**Section K: Lambert-Eaton Myasthenic Syndrome**

80. Is this request for continuation of immune globulin therapy? *If Yes, skip to #86*  Yes  No
81. 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  
 Yes – Positive anti- P/Q type voltage-gated calcium channel antibody test  
 No
82. Has the patient tried an anticholinesterase (e.g., pyridostigmine) but it was unsuccessful or not tolerated?  Yes  No
83. Has the patient tried amifampridine (eg 3,4-diaminopyridine phosphate, Firdapse) but it was unsuccessful or not tolerated?  Yes  No
84. Does the patient have severe weakness? *If Yes, no further questions.*  Yes  No
85. Is there difficulty with venous access for plasmapheresis?  Yes  No *No further questions*
86. Has the patient experienced stability or improvement in symptoms relative to the natural course of LEMS?  Yes  No

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Section L: Immune Checkpoint Inhibitor-Related Adverse Events

87. 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
88. Is the offending drug being temporarily held or has it been discontinued permanently?  Yes  No
89. Which of the following adverse events did the patient experience?
- |  |  |  |
|--|--|--|
| <input type="checkbox"/> Pneumonitis       | <input type="checkbox"/> Peripheral neuropathy | <input type="checkbox"/> Transverse myelitis           |
| <input type="checkbox"/> Myasthenia gravis | <input type="checkbox"/> Encephalitis          | <input type="checkbox"/> Severe inflammatory arthritis |
| <input type="checkbox"/> Other _____       |  |  |

Section M: Hypogammaglobulinemia from CAR-T Therapy

90. Has the patient received treatment with CAR-T therapy (e.g., tisagenlecleucel [Kymriah] or axicabtagene ciloleucel [Yescarta])?  Yes  No
91. What is the patient's 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  Unknown

Section N: Guillain-Barre Syndrome (GBS)

92. Does the patient have severe disease with significant weakness (e.g., inability to stand or walk without aid, respiratory weakness)?  Yes  No
93. Did the onset of neurologic symptoms occur less than 4 weeks from the anticipated start of immunoglobulin therapy?  Yes  No

Section O: Acute Disseminated Encephalomyelitis

94. Has the patient had an insufficient response to intravenous corticosteroid treatment?  Yes  No

Section P: Autoimmune Mucocutaneous Blistering Disease (includes Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid, and Epidermolysis Bullosa Aquisita)

95. Has the diagnosis been proven by biopsy and confirmed by pathology report?  Yes  No
96. Is the condition rapidly progressing, extensive, or debilitating?  Yes  No
97. Has the patient failed or experienced significant complications (eg diabetes, steroid-induced osteoporosis) from standard treatment (corticosteroids, immunosuppressive agents)?  Yes  No

Section Q: Autoimmune Hemolytic Anemia

98. Which type of autoimmune hemolytic anemia does the patient have?
- |                                    |                                    |                                      |
|------------------------------------|------------------------------------|--------------------------------------|
| <input type="checkbox"/> Warm type | <input type="checkbox"/> Cold type | <input type="checkbox"/> Other _____ |
|------------------------------------|------------------------------------|--------------------------------------|
99. Has the patient tried corticosteroids with inadequate response? *If Yes, no further questions.*  Yes  No
100. Has the patient has a splenectomy with inadequate response? *If Yes, no further questions.*  Yes  No
101. Does the patient have a contraindication to corticosteroids or splenectomy?  Yes  No

Section R: Autoimmune Neutropenia

102. Is treatment with G-CSF (granulocyte colony stimulating factor) an appropriate option? Examples of G-CSF include Pulphila, Granix, Leukine, Neulasta, Neuopogen, Udenyca, Zarxio.  Yes  No

Section S: Birdshot Retinochoroidopathy

103. Has the patient tried immunosuppressant therapy (e.g., corticosteroids, cyclosporine) with inadequate response?  Yes  No

Section T: Churg-Strauss Syndrome

104. Does the patient have severe, active disease?  Yes  No
105. Will immune globulin be used as adjunctive therapy?  Yes  No
106. Has the patient experienced failure, intolerance, or is contraindicated to other interventions?  Yes  No

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Section U: Enteroviral Meningoencephalitis

107. Is the patient's condition severe?  Yes  No

Section V: Hematophagocytic Lymphohistiocytosis (HLH) and Macrophage Activation Syndrome (MAS)

108. What is the patient's total IgG level? **ACTION REQUIRED: Attach a copy of the laboratory report with the pre-treatment IgG level.** \_\_\_\_\_ mg/dL *If less than 400 mg/dL, no further questions.*

109. Is the total IgG level at least two standard deviations below the mean for age?  Yes  No

Section W: Hyperimmunoglobulinemia E syndrome

110. Does the patient have severe eczema?  Yes  No

Section X: Multiple Myeloma

111. Does the patient have recurrent, serious infections despite the use of prophylactic antibiotics?  Yes  No

Section Y: Neonatal Hemochromatosis

112. Is the patient currently pregnant?  Yes  No

113. Does the patient have a history of pregnancy ending in documented neonatal hemochromatosis?  Yes  No

Section Z: Opsoclonus-Myoclonus

114. Does the patient have paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma?  
*If Yes, no further questions.*  Yes  No

115. Does the patient have refractory opsoclonus-myoclonus?  Yes  No

116. Is immune globulin being used as last-resort treatment?  Yes  No

Section AA: Rasmussen Encephalitis

117. Did the patient try anti-epileptic drugs with no improvement in symptoms?  Yes  No

118. Did the patient try corticosteroids with no improvement in symptoms?  Yes  No

Section BB: Solid Organ Transplantation

119. Is immune globulin being prescribed for solid organ transplantation in an allosensitized patient?  
*If Yes, no further questions.*  Yes  No

120. Is the patient undergoing renal transplantation from a live donor with ABO incompatibility or positive cross match?  
 Yes  No

Section CC: Secondary Immunosuppression Due to Surgery, Malignancy, Burns, Collagen-Vascular Diseases

121. Is immune globulin being requested to prevent or modify recurrent bacterial or viral infections?  Yes  No

122. 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  Unknown

Section DD: Toxic Epidermal Necrolysis, Stevens-Johnson Syndrome

123. Is the patient's case severe?  Yes  No

Section EE: Systemic Lupus Erythematosus

124. Does the patient have severe, active disease?  Yes  No

125. Has the patient experienced inadequate response, intolerance, or have a contraindication to first line therapy?  
 Yes  No

126. Has the patient experienced inadequate response, intolerance, or have a contraindication to second line therapy?  
 Yes  No

Section FF: Toxic Necrotizing Fasciitis

127. Does the patient have toxic necrotizing fasciitis due to invasive group A streptococcal infection?  
**ACTION REQUIRED: If 'yes', attach documentation confirming presence of fasciitis and culture or Gram stain.**  Yes  No

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Section GG: Toxic Shock Syndrome

128. Does the patient have toxic shock syndrome due to a staphylococcal or streptococcal infection?

**ACTION REQUIRED: If 'yes', attach culture or Gram stain.**  Yes  No

129. Is the infection refractory to several hours of aggressive therapy? *If Yes, no further questions.*  Yes  No

130. Does the patient have an undrainable focus of infection? *If Yes, no further questions.*  Yes  No

131. Does the patient have persistent oliguria with pulmonary edema?  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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