



## Xembify

### Prior Authorization Request

Your patient's benefit plan requires prior authorization for certain medications. In order to make appropriate medical necessity determinations, your patient's diagnosis and other clinical information is required. **Please complete the information requested on the form below and fax this form along with supporting clinical documentation to Priority Partners, toll-free at 1-866-212-4756 to initiate the review process.** If you have questions regarding the prior authorization please contact Priority Partners at 888-819-1043 Option 4.

**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*

**Drug Information:**

*Strength/Measure* \_\_\_\_\_ *Units*  ml  Gm  mg  ea  Un

*Directions(sig)* \_\_\_\_\_ *Route of administration* \_\_\_\_\_

*Dosing frequency* \_\_\_\_\_

**Send completed form to: Priority Partners Fax: 1-866-212-4756**

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**Site of Service Questions:**

- A. Indicate the site of service requested:  
 On Campus Outpatient Hospital  Off Campus Outpatient Hospital  
 Home based setting, *skip to Criteria Questions*  Community office, *skip to Criteria Questions*  
 Ambulatory infusion site, *skip to Criteria Questions*
- B. Is the patient less than 18 years of age?  
 Yes, *skip to Clinical Criteria Questions*  
 No
- C. 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 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
- D. 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
- E. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? ***ACTION REQUIRED: If ‘Yes’, please attach supporting clinical documentation.***  
 Yes, *skip to Clinical Criteria Questions*  No
- F. 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
- G. Has the patient’s home been deemed not eligible or appropriate for home infusion services by a home infusion provider? ***ACTION REQUIRED: If ‘Yes’, please attach supporting clinical documentation.***  
 Yes, *skip to Clinical Criteria Questions*  No
- H. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?  
***ACTION REQUIRED: If ‘Yes’, please attach supporting clinical documentation.***  Yes  No

**Clinical Criteria Questions:**

What is the ICD-10 code? \_\_\_\_\_

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 #325*  
 Chronic inflammatory demyelinating polyneuropathy (CIDP), *Continue to #100*  
 Immune thrombocytopenic purpura (ITP), *Continue to #400*  
 B-cell chronic lymphocytic leukemia (CLL), *Continue to #500*  
 Stiff-person syndrome, *Continue to #350*  
 Bone marrow transplant/hematopoietic stem cell transplant (BMT/HSCT), *Continue to #525*

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- Dermatomyositis, *Continue to #200*
- Polymyositis, *Continue to #200*
- Multifocal motor neuropathy, *Continue to #150*
- Human immunodeficiency virus (HIV) infection, *Continue to #550*
- Guillain-Barré syndrome, *Continue to #650*
- Lambert-Eaton myasthenic syndrome, *Continue to #585*
- Parvovirus B19-induced pure red cell aplasia, *Continue to #300*
- 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 #800*
- Immune checkpoint inhibitor-related toxicity, *Continue to #600*
- CAR-T therapy related hypogammaglobulinemia, *Continue to #610*
- Acquired red cell aplasia *No further questions*
- Acute disseminated encephalomyelitis, *Continue to #700*
- Rasmussen encephalitis, *Continue to #820*
- Enteroviral meningoencephalitis, *Continue to #760*
- Autoimmune mucocutaneous blistering disease (includes pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa aquisita), *Continue to #710*
- Autoimmune hemolytic anemia, *Continue to #720*
- Autoimmune neutropenia, *Continue to #730*
- Systemic lupus erythematosus, *Continue to #860*
- Birdshot retinochoroidopathy, *Continue to #740*
- BK virus associated nephropathy *No further questions*
- Churg-Strauss syndrome, *Continue to #750*
- Hematophagocytic lymphohistiocytosis (HLH), *Continue to #770*
- Macrophage Activation Syndrome (MAS), *Continue to #770*
- Hyperimmunoglobulinemia E syndrome, *Continue to #780*
- Multiple myeloma, *Continue to #790*
- Opsoclonus-myoclonus, *Continue to #810*
- Post-transfusion purpura *No further questions*
- Solid organ transplantation, *Continue to #830*
- Major surgery associated secondary immunosuppression, *Continue to #840*
- Hematologic malignancy associated secondary immunosuppression, *Continue to #840*
- Major burns associated secondary immunosuppression, *Continue to #840*
- Collagen-vascular disease associated secondary immunosuppression, *Continue to #840*
- Toxic epidermal necrolysis, *Continue to #850*
- Stevens-Johnson syndrome, *Continue to #850*

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- Toxic shock syndrome, *Continue to #880*
- Toxic necrotizing fasciitis, *Continue to #870*
- Measles (Rubeola) prophylaxis, *Continue to #900*
- Tetanus treatment and prophylaxis, *Continue to #925*
- Varicella prophylaxis, *Continue to #950*
- Other: \_\_\_\_\_

2. Is this request for continuation of immune globulin therapy?

- Yes, *Continue to #50*
- 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 #17*
- 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: \_\_\_\_\_, *Continue to #15*
- Congenital agammaglobulinemia (eg, X-linked or autosomal recessive agammaglobulinemia), *Continue to #11*
- Specific antibody deficiency, *Continue to #30*
- Other immunodeficiency disorder/none of the above: *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***

- 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, *Continue to #7*
- Greater than or equal to 200 mg/dL, *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*

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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, *Continue to #10*
- Greater than or equal to 300/microliter, *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***

- 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***

- Less than 200 mg/dL, *Continue to #14*
- Greater than or equal to 200 mg/dL, *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, *Continue to #16*
- No, *Continue to #16*
- 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?

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- 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, *Continue to #31*
- Greater than or equal to 500 mg/dL, *Continue to #20*

20. Is the patient's pretreatment IgG level  $\geq 2$  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, *Continue to #31*
- Greater than or equal to 500 mg/dL, *Continue to #22*

22. Is the patient's pretreatment IgG level  $\geq 2$  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, *Continue to #24*
- Greater than or equal to 7 mg/dL, *Continue to #24*

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***

- Less than 30 mg/dL, *Continue to #26*
- Greater than or equal to 30 mg/dL, *Continue to #26*

26. Does the patient have normal pre-treatment IgG and IgA levels?

- Yes, *Continue to #31*
- No, *Continue to #31*

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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, *Continue to #28*
- IgG2, *Continue to #28*
- IgG3, *Continue to #28*
- Other: \_\_\_\_\_, *Continue to #28*

28. Was the IgG subclass level  $\geq 2$  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***

- 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***

- 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*

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50. Has the patient experienced a reduction in the frequency of bacterial infections since starting immune globulin therapy?

- Yes, *Continue to #51*
- No, *Continue to #51*

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

- Yes, *Continue to #52*
- No, *Continue to #52*
- Not applicable for diagnosis

52. 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, *No further questions*
- No, *Continue to #53*
- Not applicable for diagnosis, *No further questions*

53. 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*

100. Is this request for continuation of immune globulin therapy?

- Yes, *Continue to #105*
- No, *Continue to #101*

101. Is the disease course progressive or relapsing/remitting for 2 months or longer?

- Yes, *Continue to #102*
- No, *Continue to #102*

102. Does the patient have moderate to severe functional disability?

- Yes, *Continue to #103*
- No, *Continue to #103*

103. 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, *Continue to #104*
- No, *Continue to #104*

104. Are the electrodiagnostic study results attached?

- Yes, *No further questions*
- No, *No further questions*

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105. Has the patient demonstrated significant improvement in disability and maintenance of improvement since starting IG therapy?

Yes, *Continue to #106*

No, *Continue to #106*

106. Is IG being used at the lowest effective dose and frequency?

Yes, *No further questions*

No, *No further questions*

150. Is this request for continuation of immune globulin therapy?

Yes, *Continue to #250*

No, *Continue to #151*

151. 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 #152*

No, *Continue to #152*

152. 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, *Continue to #153*

No, *Continue to #153*

153. Are the electrodiagnostic study results attached?

Yes, *No further questions*

No, *No further questions*

200. Is this request for continuation of immune globulin therapy?

Yes, *Continue to #251*

No, *Continue to #201*

201. Does the patient exhibit at least 4 of the following clinical features?

- 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)

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- Yes, *Continue to #202*
- No, *Continue to #202*

202. 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***

- Yes, *Continue to #204*
- No, *Continue to #203*

203. 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***

- Yes, *Continue to #204*
- No, *Continue to #204*

204. Is all required documentation attached?

- Yes, *No further questions*
- No, *No further questions*

250. 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*

251. 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*

300. Does the patient have severe, refractory anemia associated with bone marrow suppression?

- Yes, *Continue to #301*
- No, *Continue to #301*

301. Does the patient have parvovirus B19 viremia? ***ACTION REQUIRED: If 'Yes', attach test result confirming presence of parvovirus B19***

- Yes, *No further questions*
- No, *No further questions*

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

- Refractory myasthenia gravis, *Continue to #328*
- Acute exacerbation/crisis, *Continue to #326*
- Worsening weakness, *Continue to #327*
- Pre-operative management (e.g., prior to thymectomy) , *No further questions*
- Other, *No further questions* \_\_\_\_\_

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326. Does the patient have severe swallowing difficulty and/or respiratory failure?

- Yes, *No further questions*  
 No, *Continue to #327*

327. 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*

328. 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***

- Yes, *No further questions*  
 No, *No further questions*

350. Has the diagnosis been confirmed by anti-glutamic acid decarboxylase (GAD) antibody testing? ***ACTION REQUIRED: If 'Yes', attach GAD antibody test results***

- Yes, *Continue to #351*  
 No, *Continue to #351*

351. 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 further questions*  
 No, *No further questions*

400. Is the patient a pregnant woman? If yes, please provide estimated date of delivery: \_\_\_\_\_

- Yes, *No further questions*  
 No, *Continue to #401*

401. Is the patient an adult with refractory ITP after splenectomy?

- Yes, *Continue to #402*  
 No, *Continue to #404*

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

- Less than 30,000/mcL (30 x 10<sup>9</sup>/L) , *No further questions*  
 Greater than or equal to 30,000/mcL (30 x 10<sup>9</sup>/L), *Continue to #403*

403. 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*

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404. What is the classification of ITP?

- Newly-diagnosed ITP (diagnosed within the past 3 months), *Continue to #405*
- Previously untreated ITP (initial therapy), *Continue to #405*
- Chronic or persistent ITP ( $\geq 3$  months from diagnosis), *Continue to #413*
- ITP unresponsive to first-line treatment, *Continue to #413*
- Other, *No further questions*

405. What is the patient's age? \_\_\_\_\_

- Less than 18 years of age, *Continue to #406*
- 18 years of age or older, *Continue to #408*

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

- Yes, *No further questions*
- No, *Continue to #407*

407. 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, *No further questions*
- Comorbidity (e.g., peptic ulcer disease or hypertension) , *No further questions*
- Mandated anticoagulation therapy, *No further questions*
- Profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete) , *No further questions*
- Other: \_\_\_\_\_, *No further questions* \_\_\_\_\_
- No, not at high risk or does not require rapid increase in platelets, *No further questions*

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

- Less than 30,000/mcL (30 x 10<sup>9</sup>/L), *Continue to #411*
- 30,000 to less than 50,000/mcL (30 x 10<sup>9</sup> to < 50 x 10<sup>9</sup>/L), *Continue to #409*
- Greater than or equal to 50,000/mcL (50 x 10<sup>9</sup>/L) , *No further questions*

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

- Yes, *Continue to #411*
- No, *Continue to #410*

410. 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, *Continue to #411*
- Comorbidity (e.g., peptic ulcer disease or hypertension), *Continue to #411*
- Mandated anticoagulation therapy, *Continue to #411*

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Profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete), *Continue to #411*

Other: \_\_\_\_\_, *Continue to #411*

No, not at high risk or does not require rapid increase in platelets), *Continue to #411*

411. Please indicate the prescribed regimen:

IG monotherapy, *Continue to #412*

IG in combination with corticosteroid, *No further questions*

Other, *Continue to #412*

412. Is corticosteroid therapy contraindicated?

Yes, *No further questions*

No, *No further questions*

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

Less than 30,000/mcL (30 x 10<sup>9</sup>/L), *Continue to #416*

30,000 to less than 50,000/mcL (30 x 10<sup>9</sup> to < 50 x 10<sup>9</sup>/L), *Continue to #414*

Greater than or equal to 50,000/mcL (50 x 10<sup>9</sup>/L) , *No further questions*

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

Yes, *Continue to #416*

No, *Continue to #415*

415. 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, *Continue to #416*

Comorbidity (e.g., peptic ulcer disease or hypertension), *Continue to #416*

Mandated anticoagulation therapy, *Continue to #416*

Profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete), *Continue to #416*

Other: \_\_\_\_\_, *Continue to #416*

No, not at high risk or does not require rapid increase in platelets, *Continue to #416*

416. Does the patient have relapsed ITP after a previous response to IG therapy?

Yes), *Continue to #417*

No, *Continue to #417*

417. 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 further questions*

No, *No further questions*

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500. Is this request for continuation of immune globulin therapy?

- Yes, *Continue to #575*
- No, *Continue to #501*

501. Is IG prescribed for prophylaxis of bacterial infections?

- Yes, *Continue to #502*
- No, *Continue to #502*

502. Does the patient have a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization?

- Yes, *Continue to #503*
- No, *Continue to #503*

503. 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***

- Less than 500 mg/dL, *Continue to #504*
- Greater than or equal to 500 mg/dL, *Continue to #504*

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

- Yes, *No further questions*
- No, *No further questions*

525. Is this request for continuation of immune globulin therapy?

- Yes, *Continue to #575*
- No, *Continue to #526*

526. Will therapy be used to prevent the risk of acute graft-versus-host disease, associated interstitial pneumonia

- g., cytomegalovirus infections [CMV], recurrent
- Yes, *Continue to #527*
- No, *Continue to #527*

527. Has the patient received a bone marrow/hematopoietic stem cell transplant within the past 100 days?

- Yes, *No further questions*
- No, *Continue to #528*

528. 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***

- Less than 400 mg/dL, *Continue to #529*
- Greater than or equal to 400 mg/dL, *Continue to #529*

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

- Yes, *No further questions*
- No, *No further questions*

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550. Is the requested drug being prescribed for prophylaxis of bacterial infections in a pediatric patient?

Yes, *Continue to #561*

No, *Continue to #551*

551. Is the requested drug being prescribed for treatment of thrombocytopenia associated with HIV?

Yes, *Continue to #552*

No, *Continue to #552*

552. Is the patient an adult?

Yes, *Continue to #553*

No, *Continue to #557*

553. Does the patient have significant bleeding?

Yes, *Continue to #554*

No, *Continue to #554*

554. What is the patient's platelet count? \_\_\_\_\_ / mL

Less than 20,000/mL, *Continue to #555*

20,000/mL or greater, *Continue to #555*

555. Is the patient Rh-positive?

Yes, *Continue to #556*

No, *No further questions*

556. Has the patient failed treatment with RhIG?

Yes, *No further questions*

No, *No further questions*

557. 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, *Continue to #558*

Greater than or equal to 400 mg/dL, *Continue to #558*

558. 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 #559*

559. Does the patient have HIV-associated thrombocytopenia despite anti-retroviral therapy?

Yes, *No further questions*

No, *Continue to #560*

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560. What is the patient's T4 cell count? \_\_\_\_\_ / mm<sup>3</sup>

- Less than 200/mm<sup>3</sup>, *Continue to #567*
- 200/mm<sup>3</sup> or greater, *No further questions*
- Unknown, *Continue to #567*

561. Is this request for continuation of immune globulin therapy?

- Yes, *Continue to #575*
- No, *Continue to #562*

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

- Primary prophylaxis, *Continue to #563*
- Secondary prophylaxis, *Continue to #564*
- Other, *Continue to #565*

563. 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, *No further questions*
- Greater than or equal to 400 mg/dL, *Continue to #565*

564. 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 #565*

565. 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 #566*

566. 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 #567*

567. Does the patient live in an area where measles is highly prevalent?

- Yes, *Continue to #568*
- No, *Continue to #569*

568. 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 #569*

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569. Does the patient have chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy?

Yes, *No further questions*

No, *No further questions*

575. Has the patient experienced a reduction in the frequency of bacterial infections since starting IG therapy?

Yes, *No further questions*

No, *No further questions*

585. Is this request for continuation of immune globulin therapy?

Yes, *Continue to #595*

No, *Continue to #586*

586. 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, *Continue to #587*

Yes – Positive anti- P/Q type voltage-gated calcium channel antibody test, *Continue to #587*

No, *Continue to #587*

587. Has the patient tried an anticholinesterase (e.g., pyridostigmine) but it was unsuccessful or not tolerated?

Yes, *Continue to #588*

No, *Continue to #588*

588. Has the patient tried amifampridine (e.g., 3,4-diaminopyridine phosphate, Firdapse) but it was unsuccessful or not tolerated?

Yes, *Continue to #589*

No, *Continue to #589*

589. Does the patient have severe weakness?

Yes, *No further questions*

No, *Continue to #590*

590. Is there difficulty with venous access for plasmapheresis?

Yes, *No further questions*

No, *No further questions*

595. Has the patient experienced stability or improvement in symptoms relative to the natural course of LEMS?

Yes, *No further questions*

No, *No further questions*

600. 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)?

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- Yes, *Continue to #601*
- No, *Continue to #601*

601. Is the offending drug being temporarily held or has it been discontinued permanently?

- Yes, *Continue to #602*
- No, *Continue to #602*

602. 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, *No further questions*

610. 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 #611*
- No, *Continue to #611*

611. 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**

- Less than 400 mg/dL, *No further questions*
- 400 mg/dL or greater, *No further questions*
- Unknown, *No further questions*

650. Does the patient have severe disease with significant weakness (e.g., inability to stand or walk without aid, respiratory weakness)?

- Yes, *Continue to #651*
- No, *Continue to #651*

651. 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*

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700. Has the patient had an insufficient response or a contraindication to intravenous corticosteroid treatment?

Yes, *No further questions*

No, *No further questions*

710. Has the diagnosis been proven by biopsy and confirmed by pathology report?

Yes, *Continue to #711*

No, *Continue to #7111*

711. Is the condition rapidly progressing, extensive, or debilitating?

Yes, *Continue to #712*

No, *Continue to #712*

712. 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*

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

Warm type, *Continue to #721*

Cold type, *Continue to #721*

Other, *Continue to #721*

721. Has the patient tried corticosteroids with inadequate response?

Yes, *No further questions*

No, *Continue to #722*

722. Has the patient has a splenectomy with inadequate response?

Yes, *No further questions*

No, *Continue to #723*

723. Does the patient have a contraindication to corticosteroids or splenectomy?

Yes, *No further questions*

No, *No further questions*

730. Is treatment with G-CSF (granulocyte colony stimulating factor) an appropriate option?

Yes, *No further questions*

No, *No further questions*

740. Has the patient tried immunosuppressant therapy (e.g., corticosteroids, cyclosporine) with inadequate response?

Yes, *No further questions*

No, *No further questions*

750. Does the patient have severe, active disease?

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Yes, *Continue to #751*

No, *Continue to #751*

751. Will immune globulin be used as adjunctive therapy?

Yes, *Continue to #752*

No, *Continue to #752*

752. Has the patient experienced failure, intolerance, or is contraindicated to other interventions?

Yes, *No further questions*

No, *No further questions*

760. Is the patient's condition severe?

Yes, *No further questions*

No, *No further questions*

770. 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, *No further questions*

400 mg/dL or greater, *Continue to #771*

771. Is the total IgG level at least two standard deviations below the mean for age?

Yes, *No further questions*

No, *No further questions*

780. Does the patient have severe eczema?

Yes, *No further questions*

No, *No further questions*

790. Does the patient have recurrent, serious infections despite the use of prophylactic antibiotics?

Yes, *No further questions*

No, *No further questions*

800. Is the patient currently pregnant?

Yes, *Continue to #801*

No, *No further questions*

801. Does the patient have a history of pregnancy ending in documented neonatal hemochromatosis?

Yes, *No further questions*

No, *No further questions*

810. Does the patient have paraneoplastic opsoclonus-myooclonus-ataxia associated with neuroblastoma?

Yes, *No further questions*

No, *Continue to #811*

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811. Does the patient have refractory opsoclonus-myoclonus?

Yes, *Continue to #812*

No, *Continue to #812*

812. Is immune globulin being used as last-resort treatment?

Yes, *No further questions*

No, *No further questions*

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

Yes, *Continue to #821*

No, *Continue to #821*

821. Did the patient try corticosteroids with no improvement in symptoms?

Yes, *No further questions*

No, *No further questions*

830. Is immune globulin being prescribed for solid organ transplantation in an allosensitized patient?

Yes, *No further questions*

No, *Continue to #831*

831. 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*

840. Is immune globulin being requested to prevent or modify recurrent bacterial or viral infections?

Yes, *Continue to #841*

No, *Continue to #841*

841. 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***

Less than 400 mg/dL, *No further questions*

400 mg/dL or greater, *No further questions*

Unknown, *No further questions*

850. Is the patient's case severe?

Yes, *No further questions*

No, *No further questions*

860. Does the patient have severe, active disease?

Yes, *Continue to #861*

No, *Continue to #861*

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861. Has the patient experienced inadequate response, intolerance, or have a contraindication to first line therapy?

Yes, *Continue to #862*

No, *Continue to #862*

862. Has the patient experienced inadequate response, intolerance, or have a contraindication to second line therapy?

Yes, *No further questions*

No, *No further questions*

870. 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 streptococcus only) and culture or Gram stain***

Yes, *No further questions*

No, *No further questions*

880. Does the patient have toxic shock syndrome due to a staphylococcal or streptococcal infection? ***ACTION REQUIRED: If 'Yes', attach culture or Gram stain***

Yes, *Continue to #881*

No, *Continue to #881*

881. Is the infection refractory to several hours of aggressive therapy?

Yes, *No further questions*

No, *Continue to #882*

882. Does the patient have an undrainable focus of infection?

Yes, *No further questions*

No, *Continue to #883*

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

Yes, *No further questions*

No, *No further questions*

900. Is the patient susceptible and exposed to measles less than 6 days prior to this request?

Yes, *Continue to #901*

No, *Continue to #901*

901. Is this request for postexposure to prevent or modify symptoms of measles (rubeola)?

Yes, *No further questions*

No, *No further questions*

925. Is this request for treatment or postexposure prophylaxis of tetanus as an alternative when tetanus immune

Yes, *No further questions*

No, *No further questions*

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950. Is this request for treatment or postexposure prophylaxis of varicella in susceptible patients when varicella-

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 Priority Partners.*

**X**

\_\_\_\_\_  
**Prescriber or Authorized Signature**

\_\_\_\_\_  
**Date (mm/dd/yy)**

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