JOHNS HOPKINS MEDICINE
JOHNS HOPKINS HEALTHCARE

Hizentra

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

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*

❒ 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*

❒ 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*

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?

❒ 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 ≥ 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 ≥ 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*

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 ≥ 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*

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*

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)

❒ 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* _____

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 109/L) , *No further questions*

❒ Greater than or equal to 30,000/mcL (30 x 109/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*

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 (≥ 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 109/L), *Continue to #411*

❒ 30,000 to less than 50,000/mcL (30 x 109 to < 50 x 109/L), *Continue to #409*

❒ Greater than or equal to 50,000/mcL (50 x 109/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*

❒ 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 109/L), *Continue to #416*

❒ 30,000 to less than 50,000/mcL (30 x 109 to < 50 x 109/L), *Continue to #414*

❒ Greater than or equal to 50,000/mcL (50 x 109/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*

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*

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? _____ / mcL

❒ Less than 20,000/mcL, *Continue to #555*

❒ 20,000/mcL 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*

560. What is the patient's T4 cell count? _____ / mm3

❒ Less than 200/mm3, *Continue to #567*

❒ 200/mm3 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*

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)?

❒ 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*

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?

❒ 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-myoclonus-ataxia associated with neuroblastoma?

❒ Yes, *No further questions*

❒ No, *Continue to #811*

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*

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 streptococous 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*

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)**

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