Subcutaneous Immune Globulins

HMSA Medicare Advantage - Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Patient's Phone Number: _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*ft* _____*inches*

Indicate where the drug is being dispensed:

❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
❑ Psychiatric Facility ❑ Pharmacy ❑ Other

Indicate where the drug is being administered:

❑ Ambulatory surgical ❑ Home ❑ Inpatient Hospital
❑ Office ❑ Outpatient Hospital ❑ Pharmacy

What is the requested product?

❑ Cutaquig ❑ Cuvitru ❑ Hizentra
❑ HyQvia ❑ Xembify Other_____

What is the ICD-10 code? _____

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

Criteria Questions:

1. Will the requested product be administered in the patient's home?

❒ Yes, *Continue to #2*

❒ No, *Continue to #7*

2. Has the treating practitioner determined that the administration of the requested product in the patient's home is medically necessary and appropriate?

❒ Yes, *Continue to #3*

❒ No, *Continue to #3*

3. What is the diagnosis?

❒ Primary immune deficiency disorder, *Continue to #4*

❒ Chronic inflammatory demyelinating polyneuropathy, *Continue to #5*

❒ Other, *No Further Questions*

4. Is the patient receiving the requested medication for the diagnosis of primary immune deficiency disease for one of the following ICD codes?

❒ D80.0 (hereditary hypogammaglobulinemia), *No Further Questions*

❒ D80.2 (selective deficiency of immunoglobulin A [IgA]), *No Further Questions*

❒ D80.3 (selective deficiency of immunoglobulin G [IgG] subclasses), *No Further Questions*

❒ D80.4 (selective deficiency of immunoglobulin M), *No Further Questions*

❒ D80.5 (immunodeficiency with increased immunoglobulin M [IgM]), *No Further Questions*

❒ D80.6 (antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia), *No Further Questions*

❒ D80.7 (transient hypogammaglobulinemia of infancy), *No Further Questions*

❒ D81.0 (severe combined immunodeficiency [SCID] with reticular dysgenesis), *No Further Questions*

❒ D81.1 (severe combined immunodeficiency [SCID] with low T- and B-cell numbers), *No Further Questions*

❒ D81.2 (severe combined immunodeficiency [SCID] with low or normal B-cell numbers), *No Further Questions*

❒ D81.5 (purine nucleoside phosphorylase [PNP] deficiency), *No Further Questions*

❒ D81.6 (major histocompatibility complex class I deficiency), *No Further Questions*

❒ D81.7 (major histocompatibility complex class II deficiency), *No Further Questions*

❒ D81.82 (activated phosphoinositide 3-kinase delta syndrome [APDS]), *No Further Questions*

❒ D81.89 (other combined immunodeficiencies), *No Further Questions*

❒ D81.9 (combined immunodeficiency, unspecified), *No Further Questions*

❒ D82.0 (Wiskott-Aldrich syndrome), *No Further Questions*

❒ D82.1 (Di George's syndrome), *No Further Questions*

❒ D82.4 (hyperimmunoglobulin E [IgE] syndrome), *No Further Questions*

❒ D83.0 (common variable immunodeficiency with predominant abnormalities of B-cell numbers and function), *No Further Questions*

❒ D83.1 (common variable immunodeficiency with predominant immunoregulatory T-cell disorders), *No Further Questions*

❒ D83.2 (common variable immunodeficiency with autoantibodies to B- or T-cells), *No Further Questions*

❒ D83.8 (other common variable immunodeficiencies), *No Further Questions*

❒ D83.9 (common variable immunodeficiency, unspecified), *No Further Questions*

❒ G11.3 (cerebellar ataxia with defective DNA repair), *No Further Questions*

❒ Other, *No Further Questions*

5. What is the requested product?

❒ Hizentra, *Continue to #6*

❒ Other, *Continue to #6*

6. Is the patient receiving the requested medication for the diagnosis of chronic inflammatory demyelinating polyneuropathy for one of the following ICD codes?

❒ C61.81 (chronic inflammatory demyelinating polyneuritis), *No Further Questions*

❒ Other, *No Further Questions*

7. What is the diagnosis?

❒ Primary immunodeficiency (e.g., common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency, Wiskott-Aldrich syndrome), *Continue to # 10*

❒ Idiopathic thrombocytopenic purpura, *Continue to #400*

❒ Chronic inflammatory demyelinating polyneuropathy, *Continue to #100*

❒ Multifocal motor neuropathy, *Continue to #150*

❒ Kawasaki syndrome in a pediatric patient, *No Further Questions*

❒ B-cell chronic lymphocytic leukemia (CLL), *Continue to #500*

❒ Pemphigus vulgaris, *Continue to # 20*

❒ Pemphigus foliaceus, *Continue to # 20*

❒ Bullous pemphigoid, *Continue to # 20*

❒ Mucous membrane pemphigoid (cicatricial pemphigoid), *Continue to # 20*

❒ Epidermolysis bullosa acquisita, *Continue to # 20*

❒ Acquired hypogammaglobulinemia secondary to malignancy or CAR-T therapy (prevention of infections), *Continue to # 8*

❒ Acquired thrombocytopenia, *No Further Questions*

❒ Antiphospholipid syndrome, *Continue to # 8*

❒ Asthma, *Continue to # 8*

❒ Autoimmune hemolytic anemia, *Continue to # 700*

❒ Autoimmune neutropenia, *Continue to # 710*

❒ Bone marrow transplant/hemopoietic stem cell transplant, *Continue to # 525*

❒ Cerebellar ataxia due to Epstein-Barr virus infection, *Continue to # 8*

❒ Clostridium difficile colitis, *Continue to # 8*

❒ Adjunct to Crohn's disease treatment, *Continue to # 8*

❒ Cytomegalovirus treatment and prophylaxis when the member is undergoing a transplant, *Continue to # 8*

❒ Dermatomyositis, *Continue to #200*

❒ Diabetic amyotrophy, *Continue to # 8*

❒ Hopkin's syndrome, *Continue to # 8*

❒ Acute disseminated encephalomyelitis, *Continue to # 650*

❒ Prophylaxis of enteritis due to rotavirus, *Continue to # 8*

❒ Epilepsy, *Continue to # 8*
❒ Fetal or neonatal thrombocytopenia, *Continue to # 8*
❒ Gastroenteritis, *Continue to # 8*
❒ Granulomatosis with polyangiitis, *Continue to # 8*
❒ Guillain-Barre syndrome, *Continue to # 600*
❒ Hemolytic disease of fetus or newborn due to RhD isoimmunization, prophylaxis, *Continue to # 8*
❒ Hemophagocytic syndrome, *Continue to # 8*
❒ Induction of Factor VIII immune tolerance, *Continue to # 8*
❒ Moderate or severe immune checkpoint inhibitor-related adverse event, *Continue to # 550*
❒ Herpes gestationis, *Continue to # 8*
❒ Prevention of bacterial infections in HIV infected patients, *Continue to # 8*
❒ Prevention of bacterial infections in post-surgical or ICU patients, *Continue to # 8*
❒ Isaacs syndrome, *Continue to # 8*
❒ Japanese encephalitis virus disease, *No Further Questions*
❒ Severe IgA nephropathy, *Continue to # 8*
❒ Lambert-Eaton myasthenic syndrome, *Continue to #530*
❒ Linear IgA dermatosis, *Continue to # 8*
❒ Lysinuric protein intolerance, *Continue to # 8*
❒ Prevention of bacterial infections in patients with multiple myeloma, *Continue to # 725*
❒ Relapsing-remitting multiple sclerosis (RRMS), *Continue to # 8*
❒ Myasthenia gravis, *Continue to # 325*
❒ Myocarditis, *Continue to # 8*
❒ Prevention and treatment of bacterial infections in high-risk, preterm, low-birth-weight neonates, *Continue to # 8*
❒ Neonatal jaundice, *Continue to # 8*
❒ Otitis media, *Continue to # 8*
❒ Paraneoplastic visual loss, *Continue to # 8*
❒ Polyarteritis nodosa, *Continue to # 8*
❒ Polymyositis, *Continue to #200*
❒ Post-transplant lymphoproliferative disorder, *Continue to # 8*
❒ Pure red cell aplasia, *Continue to # 8*
❒ Pyoderma gangrenosum, *Continue to # 8*
❒ Renal transplant rejection, *Continue to # 8*
❒ Respiratory syncytial virus infection, *Continue to # 8*
❒ Sepsis, *Continue to # 8*
❒ Stevens-Johnson syndrome, *Continue to # 800*
❒ Stiff-person syndrome, *Continue to #350*
❒ Systemic lupus erythematosus, *Continue to # 775*
❒ Systemic onset juvenile chronic arthritis, *Continue to # 8*
❒ Systemic vasculitis, *Continue to # 8*
❒ Toxic epidermal necrolysis, *Continue to #800*

❒ Toxic shock syndrome, *Continue to # 750*

❒ Toxic necrotizing fasciitis due to Group A streptococcus (fasciitis due to invasive streptococcal infection)

❒ Heart transplant rejection, *Continue to # 8*

❒ Desensitization of highly sensitized patients awaiting renal transplantation, *Continue to # 8*

❒ Uveitis, *Continue to # 8*

❒ Von Willebrand disorder, *Continue to # 8*

❒ Desensitization therapy- heart transplant, *Continue to # 8*

❒ Measles (Rubeola) prophylaxis, *Continue to #825*

❒ Tetanus treatment and prophylaxis, *Continue to #850*

❒ Varicella prophylaxis, *Continue to #875*

❒ Other, *No Further Questions*

8. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to # 9*

❒ No, *No Further Questions*

9. Is the patient receiving benefit from therapy, such as a reduction in the frequency of infections, improvement in disability, stabilization of condition?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Primary Immune Deficiency

10. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #11*

❒ No, *No Further Questions*

11. Is the patient receiving benefit from therapy, such as a reduction in the frequency of infections, improvement in disability, stabilization of condition?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita

20. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to # 21*

❒ No, *Continue to # 22*

21. Is the patient receiving benefit from therapy, such as a reduction in the frequency of infections, improvement in disability, stabilization of condition?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

22. Was the diagnosis confirmed by biopsy?

❒ Yes, *Continue to #23*

❒ No, *Continue to #23*

23. Has the patient failed conventional therapy or is conventional therapy contraindicated?

❒ Failed conventional therapy, *Continue to # 26*

❒ Conventional therapy is contraindicated, *Continue to # 26*

❒ No, *Continue to # 24*

24. Does the patient meet both of the following: A) the member has rapidly progressive disease and B) a clinical response could not be affected quickly enough using conventional agents?

❒ Yes, *Continue to # 25*

❒ No, *Continue to #25*

25. Will immune globulin be given with conventional treatment?

❒ Yes, *Continue to # 26*

❒ No, *Continue to #26*

26. Will immune globulin be used for short-term control of the patient's condition and not as maintenance therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Chronic inflammatory demyelinating polyneuropathy (CIDP)

100. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #101*

❒ No, *No Further Questions*

Continuation criteria

101. Is the patient receiving benefit from therapy, such as a reduction in the frequency of infections, improvement in disability, stabilization of condition?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Multifocal motor neuropathy (MMN)

150. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ No, *Continue to #151*

Initial criteria: MMN

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? ***If 'yes', documentation (e.g., a copy of the EMG or NCS test results) must be submitted upon request***

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Dermatomyositis (DM) or Polymyositis (PM)

200. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ No, *Continue to #201*

Initial criteria: DM or PM

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? ***If 'Yes', documentation (e.g., supporting chart note(s) describing previous treatments) must be submitted upon request***

❒ Yes, *No Further Questions*

❒ 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? ***If 'Yes', documentation (e.g., supporting chart note(s) describing previous treatments) must be submitted upon request***

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Myasthenia gravis

325. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to # 900*

❒ No, *Continue to # 326*

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

❒ Refractory myasthenia gravis, *Continue to #329*

❒ Acute exacerbation/crisis, *Continue to #327*

❒ Worsening weakness, *Continue to #328*

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

❒ Other _____, *No Further Questions*

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

❒ Yes, *No Further Questions*

❒ No, *Continue to #328*

328. 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*

329. Has the patient tried and failed 2 or more standard therapies (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab)? ***If 'Yes', documentation (e.g., supporting chart note(s) describing previous treatments) must be submitted upon request***

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Stiff-person syndrome

350. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to # 900*

❒ No, *Continue to # 351*

351. Has the diagnosis been confirmed by anti-glutamic acid decarboxylase (GAD) antibody testing? ***If 'yes', documentation (e.g., GAD antibody test results) must be submitted upon request***

❒ Yes, *Continue to #352*

❒ No, *Continue to #352*

352. Has the patient received first-line treatment with benzodiazepines and/or baclofen and experienced an inadequate response? ***If 'Yes', documentation (e.g., supporting chart note(s) describing previous treatments) must be submitted upon request***

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Immune thrombocytopenic purpura (ITP)

400. Is the patient a pregnant woman? If yes, please provide estimated date of delivery:_____DD/MM/YYYY

❒ Yes, *No Further Questions*

❒ No, *Continue to #401*

401. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to # 900*

❒ No, *Continue to # 402*

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

❒ Yes, *Continue to #403*

❒ No, *Continue to #405*

403. What is the current pre-treatment platelet count? ***Documentation (e.g., lab report with platelet count) must be submitted upon request***

❒ 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 #404*

404. 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*

405. What is the classification of ITP?

❒ Newly-diagnosed ITP (diagnosed within the past 3 months), *Continue to #406*

❒ Previously untreated ITP (initial therapy), *Continue to #406*

❒ Chronic or persistent ITP (3 months or longer from diagnosis), *Continue to #414*

❒ ITP unresponsive to first-line treatment, *Continue to #414*

❒ Other, *No Further Questions*

406. What is the patient's age? _____

❒ Less than 18 years of age, *Continue to #407*

❒ 18 years of age or older, *Continue to #409*

Newly diagnosed children

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

❒ Yes, *No Further Questions*

❒ No, *Continue to #408*

408. 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*

Newly diagnosed adults

409. What is the current pre-treatment platelet count? ***Documentation (e.g., lab report with platelet count) must be submitted upon request***

❒ Less than 30,000/mcL (30 x 109/L), *Continue to #412*

❒ 30,000 to less than 50,000/mcL (30 x 109 to less than 50 x 109/L), *Continue to #410*

❒ Greater than or equal to 50,000/mcL (50 x 109/L), *No Further Questions*

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

❒ Yes, *Continue to #412*

❒ No, *Continue to #411*

411. 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 #412*

❒ Comorbidity (e.g., peptic ulcer disease or hypertension), *Continue to #412*

❒ Mandated anticoagulation therapy, *Continue to #412*

❒ Profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete), *Continue to #412*

❒ Other: _____, *No Further Questions*

❒ No, not at high risk or does not require rapid increase in platelets, *No Further Questions*

412. Please indicate the prescribed regimen:

❒ IG monotherapy, *Continue to #413*

❒ IG in combination with corticosteroid, *No Further Questions*

❒ Other, *No Further Questions* r

413. Is corticosteroid therapy contraindicated?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Chronic/persistent ITP

414. What is the current pre-treatment platelet count? ***Documentation (e.g., lab report with platelet count) must be submitted upon request***

❒ Less than 30,000/mcL (30 x 109/L), *Continue to #417*

❒ 30,000 to less than 50,000/mcL (30 x 109 to less than 50 x 109/L), *Continue to #415*

❒ Greater than or equal to 50,000/mcL (50 x 109/L), *No Further Questions*

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

❒ Yes, *Continue to #417*

❒ No, *Continue to #416*

416. 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 #417*

❒ Comorbidity (e.g., peptic ulcer disease or hypertension), *Continue to #417*

❒ Mandated anticoagulation therapy, *Continue to #417*

❒ Profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete), *Continue to #417*

❒ Other: _____, *No Further Questions*

❒ No, not at high risk or does not require rapid increase in platelets, *No Further Questions*

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

❒ Yes, *No Further Questions*

❒ No, *Continue to #418*

418. Does the patient have a history of inadequate response, intolerance or a contraindication to corticosteroid or anti-D therapy? ***If 'Yes', documentation (e.g., supporting chart note(s) describing previous treatments or contraindication) must be submitted upon request***

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

B-cell CLL

500. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ 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? _____ ***If IG is less than 500 mg/dL, documentation (e.g., a copy of the laboratory report with the pre-treatment IgG level) must be submitted upon request***

❒ Less than 500 mg/dL, *No Further Questions*

❒ Greater than or equal to 500 mg/dL, *No Further Questions*

BMT/HSCT transplant

525. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ No, *Continue to #526*

526. Will therapy be used to prevent the risk of acute graft-versus-host disease, associated interstitial pneumonia (infectious or idiopathic), septicemia, and other infections (e.g., cytomegalovirus infections [CMV], recurrent bacterial infection)?

❒ 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 ***If IgG is less than 400 mg/dL, documentation (e.g., a copy of the laboratory report with the pre-treatment IgG level) must be submitted upon request***

❒ Less than 400 mg/dL, *No Further Questions*

❒ Greater than or equal to 400 mg/dL, *No Further Questions*

Lambert-Eaton myasthenic syndrome (LEMS)

530. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ No, *Continue to #531*

531. Has the diagnosis been confirmed by neurophysiology studies (e.g., electromyography) or a positive anti-P/Q type voltage-gated calcium channel antibody test? ***If 'yes', documentation (e.g., a copy of the laboratory report, neurophysiology study report or other supporting medical record[s]) must be submitted upon request***

❒ Yes – Neurophysiology studies, *Continue to #532*

❒ Yes – Positive anti- P/Q type voltage-gated calcium channel antibody test, *Continue to #532*

❒ No, *Continue to #532*

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

❒ Yes, *Continue to #533*

❒ No, *Continue to #533*

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

❒ Yes, *Continue to #534*

❒ No, *Continue to #534*

534. Does the patient have severe weakness?

❒ Yes, *No Further Questions*

❒ No, *Continue to #535*

535. Is there difficulty with venous access for plasmapheresis?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Immune checkpoint inhibitor-related toxicities

550. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ No, *Continue to #551*

551. 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 #552*

❒ No, *Continue to #552*

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

❒ Yes, *Continue to #553*

❒ No, *Continue to #553*

553. 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, *No Further Questions*

❒ Toxic epidermal necrolysis, *No Further Questions*

❒ Guillain-Barre syndrome, *No Further Questions*

❒ Steroid-refractory myalgias, *No Further Questions*

❒ Myositis, *No Further Questions*

❒ Other, *No Further Questions*

Guillain-Barre Syndrome (GBS)

600. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ No, *Continue to #601*

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

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

602. 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*

Acute Disseminated Encephalomyelitis

650. Is the patient currently receiving therapy with immune globulin?
❒ Yes, *Continue to #900*
❒ No, *Continue to #651*

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

Autoimmune Hemolytic Anemia

700. Is the patient currently receiving therapy with immune globulin?
❒ Yes, *Continue to #900*
❒ No, *Continue to #701*

701. Has the patient tried corticosteroids with inadequate response?
❒ Yes, *No Further Questions*
❒ No, *Continue to #702*

702. Has the patient had a splenectomy with inadequate response?
❒ Yes, *No Further Questions*
❒ No, *Continue to #703*

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

Autoimmune Neutropenia

710. Is the patient currently receiving therapy with immune globulin?
❒ Yes, *Continue to #900*
❒ No, *Continue to #711*

711. Is treatment with G-CSF (granulocyte colony stimulating factor) an appropriate option? Examples of G-CSF include Fulphila, Granix, Leukine, Neulasta, Neupogen, Udenyca, Zarxio.
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Multiple Myeloma

725. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ No, *Continue to #726*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Toxic Shock Syndrome

750. Does the patient have toxic shock syndrome due to a staphylococcal or streptococcal infection? ***If 'yes', documentation (e.g., culture or Gram stain) must be submitted upon request***

❒ Yes, *Continue to #751*

❒ No, *Continue to #751*

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

❒ Yes, *No Further Questions*

❒ No, *Continue to #752*

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

❒ Yes, *No Further Questions*

❒ No, *Continue to #753*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Systemic Lupus Erythematosus (SLE)

775. Is the patient currently receiving therapy with immune globulin?

❒ Yes, *Continue to #900*

❒ No, *Continue to #776*

776. Does the patient have severe, active disease?

❒ Yes, *Continue to #777*

❒ No, *Continue to #777*

777. Has the patient experienced inadequate response, intolerance, or have a contraindication to first line therapy (e.g., hydroxychloroquine, glucocorticoids, anifrolumab, rituximab)?

❒ Yes, *Continue to #778*

❒ No, *Continue to #778*

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

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

Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome

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

Measles (Rubeola) prophylaxis

825. Is the patient susceptible and exposed to measles less than 6 days prior to this request?
❒ Yes, *Continue to #826*
❒ No, *Continue to #826*

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

Tetanus treatment and prophylaxis

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

Varicella prophylaxis

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

Continuation

900. Is the patient receiving benefit from therapy, such as a reduction in the frequency of infections, improvement in disability, stabilization of condition?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**