IVIG

HMSAMCD - 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?

❑ Alyglo
❑ Bivigam
❑ Gammagard Liquid
❑ Gammagard S/D
❑ Gammaplex
❑ Octagam
❑ Privigen
❑ Asceniv
❑ Flebogamma
❑ Gammagard ERC
❑ Gammaked
❑ Gamunex-C
❑ Panzyga
❑ Yimmugo
❑ Other_____

What is the ICD-10 code? _____

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

Criteria Questions:

INTRAVENOUS PRODUCTS

1. What is the diagnosis?
❒ Primary immunodeficiency (includes congenital agammaglobulinemia, X-lined agammaglobulinemia, hypogammaglobulinemia, common variable immunodeficiency, X-linked immunodeficiency with hyper IgM syndrome, severe combined immunodeficiency, and Wiskott-Aldrich syndrome), *Continue to #200*
❒ Secondary immunodeficiency due to drugs/biologic agents, underlying disease, environmental exposure, or other causes, *Continue to #200*
❒ Bone marrow/hematopoietic stem cell transplant recipient, *Continue to #1000*
❒ Human immunodeficiency virus (HIV) infection, *Continue to #1100*
❒ Chronic lymphocytic leukemia (CLL), *Continue to #1200*
❒ Chronic inflammatory demyelinating polyneuropathy (CIDP), *Continue to #300*
❒ Multifocal motor neuropathy, *Continue to #400*
❒ Guillain-Barre syndrome, *Continue to #500*
❒ Dermatomyositis, *Continue to #600*
❒ Myasthenia gravis, *Continue to #700*
❒ Pemphigus vulgaris or pemphigus foliaceus, *Continue to #800*
❒ Bullous pemphigoid or mucous membrane pemphigoid, *Continue to #800*
❒ Epidermolysis bullosa acquisita, *Continue to #800*
❒ Idiopathic thrombocytopenic purpura (ITP), *No Further Questions*
❒ Fetal alloimmune thrombocytopenia, *No Further Questions*
❒ Kawasaki syndrome, *Continue to #900*
❒ Measles (rubeola) prophylaxis, *Continue to #225*
❒ Tetanus treatment and prophylaxis, *Continue to #230*
❒ Varicella prophylaxis, *Continue to #235*
❒ Other, *No Further Questions*

Primary Immunodeficiency or Secondary Immunodeficiency

200. Is this request for a new start or continuation of therapy?
❒ New start, *Continue to #202*
❒ Continuation of therapy, *Continue to #201*

201. Was IVIG previously authorized by HMSA/CVS for this member?
❒ Yes, *Continue to #205*
❒ No, *Continue to #202*
❒ Unknown, *Continue to #202*

202. Does the member have laboratory evidence of immunoglobulin deficiency, defined as any of the following?
***ACTION REQUIRED**: Please attach a copy of the laboratory report*
- Agammaglobulinemia (total IgG less than 200 mg/dL) or
- Persistent hypogammaglobulinemia (total IgG less than 400 mg/dL, or at least two standard deviations below normal, on at least two occasions) or
- Absence of B lymphocytes

❒ Yes, *Continue to #203*

❒ No, *Continue to #203*

203. Does the member have a documented inability to mount an adequate response to inciting antigens, defined as either of the following? ***ACTION REQUIRED:*** *Please attach a copy of the laboratory report*

- Lack of appropriate rise in antibody titer following provocation with a polysaccharide antigen. For example, an adequate response to the pneumococcal vaccine may be defined as at least a 4-fold increase in titers for at least 50% of serotypes tested, or
- Lack of appropriate rise in antibody titer following provocation with a protein antigen. For example, an adequate response to tetanus/diphtheria vaccine may be defined as less than a 4-fold rise in titers 3-4 weeks after vaccine administration.

❒ Yes, *Continue to #204*

❒ No, *Continue to #204*

204. Does the member have persistent and severe infections despite treatment with prophylactic antibiotics?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Continuation Criteria

205. Has the member demonstrated a clinical response to therapy such as a reduction in bacterial infections? ***ACTION REQUIRED:*** *Please attach documentation supporting a clinical response to therapy*

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Measles (Rubeola) prophylaxis

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

❒ Yes, *Continue to #226*

❒ No, *Continue to #226*

226. 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

230. 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

235. 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*

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

300. Is this request for a new start or continuation of IVIG therapy?

❒ New start, *Continue to #302*

❒ Continuation of therapy, *Continue to #301*

301. Was IVIG previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #304*

❒ No, *Continue to #302*

❒ Unknown, *Continue to #302*

302. Does the member have significant functional disability (prior to initiating therapy)? ***ACTION REQUIRED:*** *Please attach notes documenting baseline functional disability*

❒ Yes, *Continue to #303*

❒ No, *Continue to #303*

303. Was the diagnosis of CIDP confirmed by slowing of nerve conduction velocity on electromyography (EMG) or nerve conduction studies (NCS)? ***ACTION REQUIRED****: Please attach a copy of the EMG/NCS report*

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Continuation Criteria

304. Has the member demonstrated significant clinical improvement since starting IVIG therapy (including improvement in sensory symptoms where applicable)? ***ACTION REQUIRED****: Please attach documentation (e.g., chart notes or medical records) that document clinical improvement*

❒ Yes, *Continue to #305*

❒ No, *Continue to #305*

305. What is the total duration of treatment with IVIG for CIDP?

❒ Less than 2 years, *No Further Questions*

❒ Greater than or equal to 2 years, *Continue to #306*

306. Has IVIG dose reduction or withdrawal of treatment been periodically attempted, and the effects measured, to validate continued use? ***ACTION REQUIRED:*** *Please attach documentation that describes an attempt to reduce the dose or withdraw treatment*

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Multifocal Motor Neuropathy (MMN)

400. Is this request for a new start or continuation of IVIG therapy?

❒ New start, *Continue to #402*

❒ Continuation of therapy, *Continue to #401*

401. Was IVIG previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #405*

❒ No, *Continue to #402*

❒ Unknown, *Continue to #402*

402. Was the diagnosis of MMN confirmed by demonstration of conduction block on electromyography (EMG) or nerve conduction studies (NCS)? ***ACTION REQUIRED:*** *Please attach a copy of the EMG/NCS report*

❒ Yes, *Continue to #403*

❒ No, *Continue to #403*

403. Was the diagnosis of MMN confirmed by the presence of elevated anti-GM1 antibody titers? ***ACTION REQUIRED:*** *Please attach a copy of the laboratory report*

❒ Yes, *Continue to #404*

❒ No, *Continue to #404*

404. Was conventional therapy for MMN either ineffective or not tolerated? ***ACTION REQUIRED:*** *Please attach documentation (e.g., chart notes or medical records) that document conventional therapies tried and the response*

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Continuation Criteria

405. Has the member experienced improvement in disability and maintenance of improvement with IVIG therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Guillain-Barre Syndrome

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

❒ Yes, *Continue to #501*

❒ No, *Continue to #501*

501. 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*

Dermatomyositis

600. Is this request for a new start or continuation of IVIG therapy?

❒ New start, *Continue to #602*

❒ Continuation of therapy, *Continue to #601*

601. Was IVIG previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #603*

❒ No, *Continue to #602*

❒ Unknown, *Continue to #602*

602. Did the member's condition fail to respond to first-line treatment with corticosteroids?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Continuation Criteria

603. Has the member experienced improvement in disability and maintenance of improvement with IVIG therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Myasthenia Gravis

700. Is IVIG prescribed for a member experiencing a myasthenic crisis (i.e., acute episode of respiratory muscle weakness)?

❒ Yes, *Continue to #701*

❒ No, *Continue to #702*

701. Is plasma exchange not available or is not an appropriate treatment option?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

702. Is IVIG prescribed for a member with chronic debilitating myasthenia gravis?

❒ Yes, *Continue to #703*

❒ No, *Continue to #703*

703. Is this request for a new start or continuation of IVIG therapy?

❒ New start, *Continue to #705*

❒ Continuation of therapy, *Continue to #704*

704. Was IVIG previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #706*

❒ No, *Continue to #705*

❒ Unknown, *Continue to #705*

705. Has the member experienced an inadequate response or toxicity from treatment with cholinesterase inhibitors, corticosteroids, and/or azathioprine?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Continuation Criteria

706. Has the member experienced improvement in disability and maintenance of improvement with IVIG therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Autoimmune Mucocutaneous Blistering Diseases

800. Does the member have severe progressive disease despite treatment with conventional therapy (e.g., corticosteroid, azathioprine, or cyclophosphamide)?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Kawasaki Syndrome

900. Will IVIG be used in conjunction with aspirin?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Bone Marrow/Hematopoietic Stem Cell Transplant Recipient

1000. Is this request for continuation of immune globulin therapy?

❒ Yes, *Continue to #1001*

❒ No, *Continue to #1002*

1001. Was IVIG previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #1005*

❒ No, *Continue to #1002*

❒ Unknown, *Continue to #1002*

1002. 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 infectious [CMV], recurrent bacterial infections)?

❒ Yes, *Continue to #1003*

❒ No, *Continue to #1003*

1003. Has the patient received a bone marrow/hematopoietic stem cell transplant within the past 100 days?

❒ Yes, *No Further Questions*

❒ No, *Continue to #1004*

1004. What is the patient's pre-treatment IgG level? _____ mg/dL, *No Further Questions*

Continuation Criteria

1005. Has the patient experienced a reduction in the frequency of bacterial infections since starting IG therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Pediatric HIV Infection

1100. Is IVIG prescribed to prevent infections associated with HIV infection?

❒ Yes, *Continue to #1101*

❒ No, *Continue to #1101*

1101. Is IVIG prescribed for a pediatric patient ≤ 12 years of age?

❒ Yes, *Continue to #1102*

❒ No, *Continue to #1102*

1102. Is this request for a new start or continuation of IVIG therapy?

❒ New start, *No Further Questions*

❒ Continuation of therapy, *Continue to #1103*

Continuation Criteria

1103. Has the member demonstrated a clinical response to therapy such as a reduction in bacterial infections?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Chronic Lymphocytic Leukemia (CLL)

1200. Is IVIG prescribed to prevent infections associated with CLL?

❒ Yes, *Continue to #1201*

❒ No, *Continue to #1201*

1201. Is this request for a new start or continuation of IVIG therapy?

❒ New start, *Continue to #1203*

❒ Continuation of therapy, *Continue to #1202*

1202. Was IVIG previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #1205*

❒ No, *Continue to #1203*

❒ Unknown, *Continue to #1203*

1203. Does/did the member have hypogammaglobulinemia prior to initiating IVIG therapy?

❒ Yes, *Continue to #1204*

❒ No, *Continue to #1204*

1204. Does/did the member have a history of recurrent bacterial infections prior to initiating IVIG therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Continuation Criteria

1205. Has the member demonstrated a clinical response to therapy such as a reduction in bacterial infections?

❒ 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)**

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