Clinical Policy Title:	immune Globulins
Policy Number:	RxA.143
Drug(s) Applied:	Asceniv™, Bivigam™, Cutaquig®, Cuvitru™, Flebogamma® DIF, Gamastan® S/D, Gammagard® liquid, Gammagard® S/D, Gammaked™, Gammaplex®, Gamunex®-C, Hizentra®, Octagam®, Panzyga®, Privigen®, Xembify®, Qivigy
Original Policy Date:	02/07/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. B-Cell Chronic Lymphocytic Leukemia (CLL) Infection Prophylaxis (must meet all)**:**

1. Diagnosis of B-cell CLL;
2. Recent (within the last 6 months) hypogammaglobulinemia as evidenced by two separate measurements of immunoglobulin G (IgG) level less than 500 mg/dL;
3. Member has had recurrent serious bacterial infections (e.g., requiring intravenous antibiotics, hospitalization, or consultation with an infectious disease specialist) within the past 12 months.
4. **Approval duration**

All Lines of Business (except Medicare): 6 months

B. Dermatomyositis (DM) or Polymyositis (PM) (off-label) (must meet all)**:**

1. Diagnosis of dermatomyositis (DM) or polymyositis (PM);
2. Request is for Octagam 10%;
3. Trial and failure of 4-months of a systemic corticosteroid (e.g., prednisone) in combination with one of the following immunosuppressive agents, both at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced (a, b, c, d, e, or f):
    a. Methotrexate
    b. Azathioprine
    c. Cyclophosphamide
    d. Mycophenolate mofetil
    e. Tacrolimus,
    f. Cyclosporine ;
4. For dermatomyositis requests, member has tried and failed rituximab, unless contraindicated, clinically significant adverse effects are experienced, or the member is diagnosed with juvenile dermatomyositis plus calcinosis.
5. **Approval duration**

All Lines of Business (except Medicare): 6 months

C. Fetal/Neonatal Alloimmune Thrombocytopenia (FNAIT) (off-label) (must meet all)**:**

1. Diagnosis of fetal/neonatal alloimmune thrombocytopenia (FNAIT);
2. Member meets one of the following (a, b, c, or d):

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a. Previous pregnancy affected by FNAIT;
b. Serological confirmation of FNAIT as evidenced by maternal-fetal HPA incompatibility;
c. Nadir platelet count < 100 x 10^9/L at birth or within 7 days after birth of the affected child;
d. Fetal intracranial hemorrhage.

3. **Approval duration**

All Lines of Business (except Medicare): 6 months

D. Acute Inflammatory Demyelinating Polyneuropathy (AIDP) (also known as Guillain-Barre Syndrome (GBS)) or Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (must meet all):

1. Diagnosis of AIDP (GBS) or CIDP;
2. Member meets one of the following (a - b):
   a. Diagnosis of AIDP/GBS and member meets one of the following (i-vii):
      i. Inability to stand or walk at least 30 feet without assistance;
      ii. ICU admission required for aspiration or mechanical ventilation;
      iii. Miller-Fisher syndrome;
      iv. Inability to raise head against gravity;
      v. Severe bulbar palsy (e.g., impaired gag reflex, dysarthria and/or dysphagia);
      vi. Bilateral facial weakness;
      vii. Autonomic dysfunction (e.g., unexplained dysrhythmia, blood pressure fluctuations, significant bowel or bladder involvement);
   b. Diagnosis of CIDP and member meets all of the following (i-v):
      i. Disease is progressive or relapsing for more than 2 months;
      ii. Member has one of the following (a or b):
         a. Memebr meets both of the following characterizing typical CIDP (1 and 2):
            1. Chronically progressive, stepwise, or recurrent symmetric proximal and distal weakness and sensory dysfunction of all extremities;
            2. Absent or reduced tendon reflexes in all extremities;
         b. Member meets one of the following characterizing atypical CIDP (1, 2, or 3):
            1) Predominantly distal (distal acquired demyelinating symmetric, DADS) or asymmetric [multifocal acquired demyelinating sensory and motor neuropathy (MADSAM), Lewis-Sumner syndrome] or focal (e.g., involvement of the brachial or lumbosacral plexus or of one or more peripheral nerves in one upper or lower limb) disease;
            2) Pure motor symptoms;
            3) Pure sensory symptoms (including chronic immune sensory polyradiculopathy affecting the central process of the primary sensory neuron);
      iii. Diagnosis has been confirmed via electrodiagnostic testing;
      iv. Member does not have any of the following (1, 2, 3, 4, 5, and 6):
         1) Borrelia burgdorferi infection (Lyme disease), diphtheria, drug or toxin exposure probably to have caused the neuropathy;
         2) Hereditary demyelinating neuropathy;
         3) Prominent sphincter disturbance;
         4) Diagnosis of multifocal motor neuropathy;
         5) IgM monoclonal gammopathy with high titre antibodies to myelin-associated glycoprotein;
         6) Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, diabetic and nondiabetic lumbosacral radiculoplexus neuropathy;
      v. For members who do not have pure motor symptoms, failure of at least one corticosteroid (e.g., prednisone) at up to maximally indicated doses unless contraindicated or clinically

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significant adverse effects are experienced.

3. **Approval duration**

All Lines of Business (except Medicare): 6 months

E. Idiopathic Thrombocytopenic Purpura (ITP), Acute or Chronic (must meet all)**:**

1. Diagnosis of ITP;
2. The request meets one of the following (a or b):
   a. For chronic ITP, the request is for Flebogamma® 10%, Gammagard S/D®, Gammaked™, Gammaplex®, Gamunex C®, Octagam 10%, Panzyga® or Privigen®;
   b. For acute ITP, the request is for Gammaked™or Gamunex C®;
3. Member meets one of the following (a or b):
   a. Trial and failure of one of the following at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced (i or ii):
      i. Systemic corticosteroids (e.g., prednisone);
      ii. Rho(D) immune globulin (RhIG);
      *Prior authorization is required for RhIG;
   b. Member is pregnant;
4. Member meets one of the following conditions (a, b, c, d, or e):
   a. Acute bleeding due to severe thrombocytopenia (platelet count less than 30,000/µL);
   b. Severe thrombocytopenia (platelet counts less than 20,000/µL) and considered to be at risk for intracerebral hemorrhage;
   c. Platelet counts persistently at or below 20,000/µl (For CITP);
   d. Splenectomy is scheduled;
   e. Member is pregnant.
5. **Approval duration**

All Lines of Business (except Medicare): 6 months

F. Kawasaki Syndrome Aneurysm Prevention (must meet all)**:**

1. Diagnosis of Kawasaki Syndrome or Incomplete (Atypical) Kawasaki Disease;
2. Prescribed concurrently with aspirin therapy, unless contraindicated or clinically significant adverse effects are experienced.
3. **Approval duration**

All Lines of Business (except Medicare): 1 month

G. Kidney Transplant (off-label) (must meet all)**:**

1. Member meets one of the following (a or b):
   a) If prescribed prior to kidney transplant, member has high levels of “anti-donor” antibodies (i.e., member is highly sensitized to the tissue of the majority of living or cadaveric donors because of “non-self” human leukocyte antigen (HLA) or ABO incompatibility);
   b) If prescribed following kidney transplant, used for the treatment of antibody- mediated rejection.
2. **Approval duration**

All Lines of Business (except Medicare): 6 months

H. Multifocal Motor Neuropathy (MMN) (must meet all)**:**

1. Diagnosis of MMN.
2. **Approval duration**

All Lines of Business (except Medicare): 6 months

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I. **Multiple Myeloma (MM) Infection Prophylaxis (off-label)** (must meet all)**:**
1. Diagnosis of multiple myeloma (MM) with stable plateau phase disease;
2. Recent (within the last 6 months) hypogammaglobulinemia as evidenced by two separate measurements of immunoglobulin G (IgG) level less than 400 mg/dL;
3. Member has had recurrent serious bacterial infections (e.g., requiring intravenous antibiotics, hospitalization, or consultation with an infectious disease specialist) within the past 12 months;
4. Documented failure or inability to tolerate chemotherapy or radiation therapy.
5. **Approval duration**

All Lines of Business (except Medicare): 6 months

J. **Multiple Sclerosis (MS) (off-label)** (must meet all)**:**
1. Diagnosis of relapsing-remitting multiple sclerosis (MS);
2. Trial and failure of three FDA-approved disease-modifying MS therapies (e.g., Avonex, Betaseron, Copaxone, Vumerity, Kesimpta) at up to maximally indicated doses unless contraindicated or clinically significant side effects are experienced.
   *Prior authorization is required for MS therapies.
3. **Approval duration**

All Lines of Business (except Medicare): 6 months

K. **Myasthenia Gravis (MG)/Lambert Eaton Myasthenic Syndrome (LEMS) (off-label)** (must meet all)**:**
1. Diagnosis of myasthenia gravis (MG) or Lambert Eaton myasthenic syndrome (LEMS);
2. Member meets one of the following conditions (a, b, or c):
   a) Acute crisis (e.g., vital capacity less than 1 L/min, inability to walk 100 ft without assistance, intubation, dysphagia with aspiration, mechanical ventilation);
   b) Thymectomy surgery is scheduled;
   c) Trial and failure of both of the following at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (i and ii):
      i. Amifampridine or a cholinesterase inhibitor (e.g., pyridostigmine) for LEMS;
      ii. Systemic corticosteroid (e.g., prednisone) or immunosuppressant (e.g., azathioprine) for MG.

   *Prior authorization may be required for amifampridine.
3. **Approval duration**

All Lines of Business (except Medicare): 6 months

L. **Paraneoplastic Neurological Syndrome (off-label)** (must meet all)**:**
1. Diagnosis of one of the following subtypes of paraneoplastic neurological syndrome (a or b):
   a. Opsoclonus-myoclonus syndrome;
   b. Anti-NMDA encephalitis;
2. For opsoclonus-myoclonus syndrome, member has tried and failed at least one systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced.
3. **Approval duration**

All Lines of Business (except Medicare): 6 months

M. **Parvovirus B19 Infection and Anemia (off-label)** (must meet all)**:**
1. Diagnosis of anemia secondary to chronic parvovirus B19 infection;
2. Recent (within the last 30 days) severe anemia (i.e., Hgb <10 or Hct < 30) due to bone marrow suppression.

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3. **Approval duration**

All Lines of Business (except Medicare): 6 months

N. Pediatric Human Immunodeficiency Virus (HIV) Infection Prophylaxis (off-label) (must meet all)**:**

1. Prescribed for prophylaxis of serious bacterial infection in a child who has human immunodeficiency virus (HIV);
2. Recent (within the last 6 months) hypogammaglobulinemia as evidenced by two separate measurements of serum IgG concentration less than 250 mg/dL;
3. Member meets one of the following conditions (a, b, c, d, or e):
   a) Recurrent serious bacterial infections (defined as two or more infections such as bacteremia, meningitis, or pneumonia in a 12-month period);
   b) Inadequate antibody response to protein/polysaccharide antigens (e.g., measles, pneumococcal, and/or Haemophilus influenzae type b);
   c) Lives in an area where measles is highly prevalent and has not developed an antibody response after two doses of measles, mumps, and rubella virus live vaccine;
   d) Exposure to measles (requires a single dose);
   e) Chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy.
4. **Approval duration**

All Lines of Business (except Medicare): 6 months

O. Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid (also known as Cicatricial Pemphigoid), Epidermolysis Bullosa Acquisita (off-label) (must meet all):

1. Diagnosis of one of the following (a, b, c, d, or e):
   a) Pemphigus vulgaris;
   b) Pemphigus foliaceus;
   c) Bullous pemphigoid;
   d) Mucous membrane pemphigoid (also known as cicatricial pemphigoid);
   e) Epidermolysis bullosa acquisita;
2. Trial and failure of at least one corticosteroid (e.g., prednisone) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Trial and failure of at least one immunosuppressive agent (e.g., cyclophosphamide, azathioprine, mycophenolate mofetil) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Trial and failure of Rituxan® unless contraindicated or clinically significant adverse effects are experienced.

   Approval duration

All Lines of Business (except Medicare): 6 months

P. Primary Immunodeficiencies (PI) (must meet all)**:**

1. Diagnosis of primary immunodeficiencies (PI), including any of the following (a, b, c, d, e, f, g, or h):
   a) Agammaglobulinemia (e.g., X-linked, congenital);
   b) Common variable immunodeficiency (CVID);
   c) Congenital hypogammaglobulinemia;
   d) Immunodeficiency with near/normal IgM (absent IgG, IgA) (also known as Hyper IgM syndrome);
   e) Selective immunodeficiency (e.g., selective IgA, IgM, or IgG subclass);
   f) Severe combined immunodeficiency disorders (SCID) (e.g., X-SCID, jak3, ZAP70, adenosine deaminase (ADA) deficiency, PNP, RAG defects, Ataxia Telangiectasia, Wiskott-Aldrich syndrome,

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DiGeorge syndrome);
g) Subclass deficiency;
h) Functional/specific antibody deficiency;

2. Member meets one of the following (a or b):
   a) For functional/specific antibody deficiency, member meets all of the following (i, ii, and iii):
      i. Normal immune globulin levels;
      ii. Inadequate antibody response to polysaccharide antigens (e.g., pneumococcal);
      iii. Recurrent sinopulmomary infections within the past 12 months;
   b) Recent (within the last 6 months) total or subclass immune globulin deficiency (below normal for age) as evidenced by two separate measurements of immunoglobulin level and one of the following (i, ii, iii, or iv):
      i. For ADA-SCID,trial and failure (defined as experiencing continued recurrent serious bacterial infections) of Revcovi®, or hematopoietic stem cell transplant, unless contraindicated or clinically significant adverse effects are experienced;
      ii. SCID (not including ADA-SCID);
      iii. Recurrent serious bacterial infections (e.g., requiring intravenous antibiotics, hospitalization, or consultation with an infectious disease specialist) within the past 12 months;
      iv. Inadequate antibody response to protein/polysaccharide antigens (e.g., tetanus, diphtheria, pneumococcal).
3. **Approval duration**

All Lines of Business (except Medicare): 6 months

Q. Stiff Person Syndrome (off-label) (must meet all)**:**

1. Diagnosis of stiff person syndrome (also known as Moersch-Woltmann syndrome);
2. Trial and failure of a benzodiazepine (e.g., diazepam) or baclofen at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced.
3. **Approval duration**

All Lines of Business (except Medicare): 6 months

R. Viral Prophylaxis for Hepatitis A, Measles, Varicella, Rubella Viruses (must meet all):

1. Request is for intramuscular formulation;
2. Request is for one of the following indications (a, b, c, or d):
   a) Hepatitis A post-exposure/high-risk prophylaxis and meets both of the following (i and ii):
      i. Hepatitis A exposure or at high risk for exposure as evidenced by (a or b):
         a. Exposure to hepatitis A in the past 2 weeks (e.g., household contact, sexual contact, sharing illicit drugs with someone positive for hepatitis A, regular babysitters/caretakers, food handlers at the same establishment as one who is positive for hepatitis A) and does not have clinical manifestations of hepatitis A;
         b. Traveling to or working in an area endemic for hepatitis A;
      ii. Meets at least one of the following (a, b, or c):
         a. Hepatitis A vaccine is locally unavailable;
         b. History of severe allergic reaction (anaphylaxis) to the hepatitis A vaccine;
         c. If either exposed to the virus or traveling in ≤ 2 weeks to an area endemic for hepatitis A, then (1, 2, or 3):
            1. Age < 1 year or > 40 years;
            2. Chronic liver disease or other chronic medical condition;
            3. Immunocompromised;

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b) Measles (rubella) post-exposure prophylaxis and meets all of the following (i, ii, iii, and iv):
   i. Exposure to measles within the past 6 days;
   ii. Member has not previously received a measles vaccine;
   iii. Member has not previously had measles;
   iv. Meets at least one of the following (a, b, c, d, e, or f):
      a. Measles vaccine is locally unavailable;
      b. History of severe allergic reaction (anaphylaxis) to the measles vaccine;
      c. Pregnancy;
      d. Immunocompromised;
      e. Has been > 3 days since exposure;
      f. Age < 12 months;

c) Chickenpox (varicella) post-exposure prophylaxis and meets all of the following (i, ii, iii, and iv):
   i. Exposure to varicella within the past 10 days;
   ii. Member lacks immunity to varicella;
   iii. Varicella zoster immune globulin (VZIG) is currently unavailable;
   iv. Meets any of the following (a, b, c, d, or e):
      a. Varicella vaccine is locally unavailable;
      b. History of a severe allergic reaction (anaphylaxis) to the varicella vaccine;
      c. Pregnancy;
      d. Immunocompromised;
      e. Newborn of mother who had varicella from 5 days before to 2 days after delivery;

d) Rubella post-exposure prophylaxis (i and ii):
   i. Recent exposure to rubella;
   ii. Member is pregnant.

2. Approval duration

All Lines of Business (except Medicare): Hepatitis A: 6 months; All other indications: One-time approval (1 month)

S. Management of Immunotherapy-Related Toxicities (CAR T-Cell-Related Toxicities) (off-label) (must meet all):
1. Diagnosis of Immunotherapy-Related Toxicities (CAR T-Cell-Related Toxicities);
2. Member has serum IgG levels <400-600 mg/dL;
3. Serious or recurrent infections [particularly bacterial].
4. **Approval Duration**

All Lines of Business (except Medicare): 6 months

T. Management of Immunotherapy-Related Toxicities (Immune Checkpoint Inhibitor-Related Toxicities) (off-label) (must meet all):
1. Diagnosis of Immunotherapy-Related Toxicities (Immune Checkpoint Inhibitor-Related Toxicities);
2. Member meets one of the following (a, b, c, d, e, f, g, h, or i):
   a. Additional therapy for suspected myocarditis if no improvement within 24 hours of starting pulse-dose methylprednisolone;
   b. Severe (G3) or life-threatening (G4) bullous dermatitis;
   c. Stevens-Johnson syndrome, or toxic epidermal necrolysis;
   d. Moderate, severe, or life-threatening steroid-refractory myalgias or myositis;
   e. Severe (G3-4) myasthenia gravis;
   f. Moderate (G2) or severe (G3-4) Guillain-Barré Syndrome or severe (G3-4) peripheral neuropathy in combination with pulse-dose methylprednisolone;

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g. Encephalitis in combination with pulse-dose methylprednisolone if severe or progressing symptoms, or if oligoclonal bands present;
h. Transverse myelitis;
i. Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone.

3. **Approval Duration**

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Kawasaki Syndrome/Incomplete (Atypical) Kawasaki Disease, Viral Prophylaxis (Hep A, Measles, Varicella, Rubella), Management of Immunotherapy-Related Toxicities (Immune Checkpoint Inhibitor-Related Toxicities), **Management of Immunotherapy-Related Toxicities (CAR T-Cell-Related Toxicities)**

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): Not applicable

B. All Other Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

2. Approval Duration

All Lines of Business (except Medicare): 12 months

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28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Reviewed criteria and updated dosing information	04/2020	
Policy was reviewed: 1) Initial Approval Criteria-Approval duration updated for commercial 2) Continuation therapy criteria II.A.1. rephrased to "Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy 3) References were updated.	02/10/2021	03/09/2021
Policy was reviewed: 1. Policy updated to remove drug Carimune NF as it is no longer available. 2. Initial Approval Criteria, a. I.E.1: Updated indication from Diagnosis of acute or chronic ITP to Diagnosis of ITP. b. I.A.E.2: Updated to include new indication criteria Member meets one of the following (a-b): a. Chronic ITP: If request is for Flebogamma® 10%, Gammagard S/D®, Gammaked™, Gammaplex®, Gamunex C®, Octagam 10%, Panzyga®, Privigen b. Acute ITP: Gammaked™, Gamunex C® c. I.D.5.b: Updated Dose criteria from For CIDP: Loading dose 2 g per kg Intravenous given in divided doses over two to four consecutive days, following by maintenance dose of 1 g per kg IV every 3 weeks;to For CIDP: Gammaked™, Gamunex®-C; Loading dose 2 g per kg Intravenous given in divided doses over two to four consecutive days, following by maintenance dose of 1 g per kg IV every 3 weeks. d. I.B.2: Updated to include Request for Octagam 10%; e. Initial Approval Criteria, I.E.3: Updated to include new age criteria Member meets one of the following (a or b or c): a) Octagam 10% , Gammaked®, Gammagard S/D®, Gamunex C®: Age at least 18 years or older b) Privigen®: Age at least 15 years or older c) Flebogamma®, Gammaplex®: 10%: 2 years of age and older	12/15/2021	01/17/2022

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f. I.P.3: Updated to include new age criteria Meet one of the following (a, b or c)
   a. Asceniv™: Age 12 to 17 years
   b. Octagam®, Bivigam™: Age at least 6 years or older
   c. Xembify®, Panzyga®, Hizentra®, Gamunex®-C, Gammaplex®, Gammaked™, Gammagard® S/D, Gammagard® liquid, Flebogamma® DIF, Cuvitru™ Cutaquig®: Age at least 2 years or older
g. I.S: Updated to include approval criteria for indication, Management of Immunotherapy-Related Toxicities (CAR T-Cell-Related Toxicities)
h. I.T: Updated to include approval criteria for indication, Management of Immunotherapy-Related Toxicities (Immune Checkpoint Inhibitor-Related Toxicities)
i. E.6: Updated to add a.Acute bleeding due to severe thrombocytopenia (platelet count less than 30,000/ µL), b. In patients with severe thrombocytopenia(platelet counts less than 20,000/ µL) considered to be at risk for intracerebral hemorrhage; c. Platelets counts persistently at or below 20,000/ µL(for CITP);
j. I.5:Updated to add ,"documented failure or inability to tolerate chemotherapy or radiation therapy".
k. K.3.C.i and K.3.C.ii updated to add for LEMS and for MG respectively.
l. N.3 updated serum IgG concentration to less than 250 mg/dl from 400 mg/dl.

3. All Initial Approval Criteria were updated to remove requirement: Member meets one of the following (a or b): a.Request is for Gammagard unless there is a specific health plan-preferred* immune globulin product; b. Failure of Gammagard (or health plan-preferred* immune globulin product) unless contraindicated or clinically significant adverse effects are experienced; *Immune globulin products are generally interchangeable, and it is at the health plan's discretion to prefer a clinically appropriate alternative product based on the time of request.

4. Continued Therapy Approval Crtieria, IIA updated from Kawasaki Syndrome/Incomplete (Atypical) Kawasaki Disease, Viral Prophylaxis (Hep A, Measles, Varicella, Rubella) to Kawasaki Syndrome/Incomplete (Atypical) Kawasaki Disease, Viral Prophylaxis (Hep A, Measles, Varicella, Rubella), Management of Immunotherapy-Related Toxicities (Immune Checkpoint Inhibitor-Related

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Toxicities), Management of Immunotherapy-Related Toxicities (CAR T-Cell-Related Toxicities). 5. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.D.3: Updated to include new diagnostic criteria "Member meets one of the following (a - b): a. Diagnosis is AIDP/GBS and member meets one of the following (i-vii): i. Inability to stand or walk at least 30 feet without assistance; ii. ICU admission required for aspiration or mechanical ventilation; iii. Miller-Fisher syndrome; iv. Inability to raise head against gravity; v. Severe bulbar palsy (e.g., impaired gag reflex, dysarthria and/or dysphagia); vi. Bilateral facial weakness; vii. Autonomic dysfunction (e.g., unexplained dysrhythmia, blood pressure fluctuations, significant bowel or bladder involvement); b. Diagnosis is CIDP and member meets all of the following (i-v): i. Disease is progressive or relapsing for more than 2 months; ii. Member has either of the following (a or b): a. Both of the following, characterizing typical CIDP (1 and 2): 1. Chronically progressive, stepwise, or recurrent symmetric proximal and distal weakness and sensory dysfunction of all extremities; 2. Absent or reduced tendon reflexes in all extremities; b. One of the following, characterizing atypical CIDP (1-3): 1. Predominantly distal (distal acquired demyelinating symmetric, DADS) or asymmetric [multifocal acquired demyelinating sensory and motor neuropathy (MADSAM), Lewis-Sumner syndrome] or focal (e.g., involvement of the brachial or lumbosacral plexus or of one or more peripheral nerves in one upper or lower limb) disease; 2. Pure motor symptoms; 3. Pure sensory symptoms (including chronic immune sensory polyradiculopathy affecting the central process of the primary sensory neuron); iii. Diagnosis has been confirmed via electrodiagnostic	11/03/2022	01/17/2023

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testing. iv. Member does not have any of the following (1-6): 1. Borrelia burgdorferi infection (Lyme disease), diphtheria, drug or toxin exposure probably to have caused the neuropathy; 2. Hereditary demyelinating neuropathy; 3. Prominent sphincter disturbance; 4. Diagnosis of multifocal motor neuropathy; 5. IgM monoclonal gammopathy with high titre antibodies to myelin-associated glycoprotein; 6. Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, diabetic and nondiabetic lumbosacral radiculoplexus neuropathy; v. For members who do not have pure motor symptoms, failure of at least one corticosteroid (e.g., prednisone) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced; 2. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed “Hyqvia” from the PA policy. 2. Removed age restrictions. 3. Removed prescriber restrictions. 4. Removed dose restrictions. 5. Updated approval duration for indications CAR T-Cell-Related Toxicities and Immune Checkpoint Inhibitor-Related Toxicities to 6 months. 6. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 7. Removed reauthorization requirement for positive response to therapy. 8. Updated approval duration verbiage. 9. References were updated.	8/28/2024	9/13/2024

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