SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Immune Globulin Intravenous (IVIG) (Medical)
(Miscellaneous Disorders)

PREFERRED	
❑ **Bivigam®** [Immune Globulin Intravenous (Human), 10% Liquid] **(J1556)**	❑ **Gammaked™** [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] **(J1561)**
❑ **Flebogamma® DIF** [Human Normal Immunoglobulin (IVIg)] **(J1572)**	❑ **Gamunex®-C** [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] **(J1561)**
❑ **Gammagard® Liquid** [Immune Globulin Infusion (Human), 10% Solution, for intravenous and subcutaneous administration] **(J1569)**	❑ **Octagam®** [Immune Globulin Intravenous (Human) liquid preparation] **(J1568)**
❑ **Gammagard® S/D** [Immune Globulin Intravenous (Human) Solvent/Detergent Treated (Freeze-Dried Concentrate)] **(J1566)**	❑ **Privigen®** [Immune Globulin Intravenous (Human), 10% Liquid] **(J1459)**
NON-PREFERRED	
❑ **Panzyga®** [Immune Globulin Intravenous (Human) – ifas 10% Liquid Preparation] **(J1576)**	

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

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DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Height: _____**inches** **Weight (last 30 days):** _____

Dosing should be calculated using adjusted body weight if the member's actual body weight is **20% higher** than his or her ideal body weight (IBW).

(Adjusted body weight = IBW + 0.5 (actual body weight – IBW)

- IBW (kg) for males = 50 + [2.3 (height in inches – 60)]
- IBW (kg) for females = 45.5 + [2.3 x (height in inches – 60)]

***IMPORTANT* - If recommended adjusted body weight is not accepted, a PARTIAL approval will be granted.**

It is recommended to attempt to decrease/wean the dose for renewal requests when improvement has occurred and subsequently stop IVIG therapy if improvement is sustained with a dose reduction (this does **NOT** apply to authorizations for Primary Immunodeficiency (PID) as long as immunoglobulin levels are maintained in the appropriate range).

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

CLINICAL CRITERIA/DIAGNOSIS: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ For all diagnoses below, all clinical criteria must be met **AND** if requesting non-preferred Panzyga, member must have a 90-day trial & failure of **three (3)** preferred IVIG products **(documentation of treatment failure must be submitted with request)**

❑ **Diagnosis - Autoimmune blistering disorders.**
Initial Approval – 3 months (Dose: 2g/kg divided over 2-5 days.)
Renewal Approval – 6 months; renewal is based on progress notes, status post-initial dose, and if autoimmune blistering disorder is still present.

- Check box below for **one** of the diagnoses:

❑ Bullous Pemphigoid	❑ Epidermolysis Bullosa Acquisita
❑ Pemphigoid (a.k.a. Cicatricial Pemphigoid)	❑ Pemphigus Foliaceus
❑ Pemphigus Vulgaris	

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- Both boxes below must be checked.
  - ❑ Failure, contraindication, or intolerance of conventional therapy with high dose corticosteroids **and** one immunosuppressant therapies (e.g., azathioprine, cyclophosphamide, mycophenolate, methotrexate)

    AND
  - ❑ Rapidly progressive disease in which a clinical response cannot be affected quickly enough using conventional drugs

❑ **Diagnosis - Immune Thrombocytopenic Purpura (ITP). For ONE (1) treatment. If another treatment is warranted, PA must be resubmitted.** (Dose: 2g/kg divided over 5 days **OR** 1g/kg once daily for 2 consecutive days in a 28-day cycle)

- ❑ Platelet count <30; **OR**
- ❑ Platelet count <50 w/ bleed; **AND**
- ❑ Trial and failure of high dose steroid for 7 days

❑ **Diagnosis - Acute exacerbation Myasthenia Gravis.**
Authorized Approval - ONE month only; submit status report.* (Dose: 1-2g/kg divided as either 0.5g/kg daily x 2 days **OR** 0.4g/kg daily x 5 days, one course)
PLEASE NOTE: IVIG is not covered for maintenance therapy.

- ❑ Member has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; **AND**
- ❑ Member has an acute exacerbation (within last 60 days) resulting in impending myasthenic crisis (i.e., respiratory compromise, acute respiratory failure, and/or bulbar compromise); **AND**
- ❑ Member is failing on conventional immunosuppressant therapy high dose corticosteroids **AND** one of the following **within the last four (4) months**: azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide; **AND**
- ❑ Member will be on combination therapy with corticosteroids or other immunosuppressants (e.g., azathioprine, mycophenolate, cyclosporine, methotrexate, tacrolimus, cyclophosphamide)

❑ **Diagnosis - Lambert-Eaton Myasthenic Syndrome.**
Initial Approval - 6 months.
Renewal – 12 months if diagnosis still present.

- ❑ Member has a history of failure, contraindication, or intolerance to a high dose corticosteroid; **AND**
- ❑ Member has a history of failure, contraindication, or intolerance to an immunomodulatory monotherapy (e.g., azathioprine, cyclophosphamide, mycophenolate, methotrexate); **AND**
- ❑ Medication will be used with concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids) for long-term management unless contraindicated

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- ❑ **Diagnosis - PANDAS** (Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcus Infections).
  Authorized Approval – 12 months

- ❑ **Diagnosis - Prevention/Treatment of Solid Organ** (kidney, liver, lung, heart, and pancreas) **Transplant Rejection.**
  Authorized Approval - 3 months (Dose: 2g/kg divided over 5 days, 28 days).
  - ❑ Coverage is provided for one or more of the following (list is not all-inclusive).
  - ❑ Suppression of panel reactive anti-human leukocyte antigen (HLA) antibodies prior to transplantation
  - ❑ Treatment of antibody-mediated rejection of solid organ transplantation
  - ❑ Prevention or treatment of viral infections (e.g., cytomegalovirus, Parvo B-19 virus, and Polyoma BK virus)

- ❑ **Diagnosis - Dermatomyositis/Polymyositis.**
  Authorized Approval - 6 months (Dose: 2g/kg divided over 2-5 days, 28 days).
  - ❑ **Member has severe active disease.**
  - ❑ **DERMATOMYOSITIS** – extramuscular manifestations of the antisynthetase syndrome including rash [such as Gottron's papules or a heliotrope rash), polyarthritis, Raynaud phenomenon, and interstitial lung disease, particularly if an antisynthetase antibody (most often anti-Jo-1) is present and marked elevation of muscle enzymes]

    OR

  - ❑ **POLYMYOSITIS**

    AND

  - ❑ Member has proximal weakness in all upper and/or lower limbs; **AND**
  - ❑ Diagnosis has been confirmed by muscle biopsy **(choose one below) (must submit biopsy results)**:
    - ❑ **Dermatomyositis biopsy** – evidence of injury to capillaries and perifascicular myofibers and abnormal muscle fibers are usually grouped in one portion of the fascicle, suggestive of microinfarction mediated by blood vessel dysfunction

      OR

    - ❑ **Polymyositis biopsy** – cellular infiltrate is predominantly within the fascicle, with inflammatory cells invading individual muscle fibers **AND** abnormal necrotic and regenerating muscle fibers are scattered throughout the fascicle and are not limited to one portion; **AND**
  - ❑ Member has failed a trial (verify through paid claims) of high dose corticosteroids (Prednisone 0.5-1 mg/kg/day for 2 – 4 weeks) **within the last 4 months** and document failure in progress notes; **AND**
  - ❑ Member has failed a trial (verify through paid claims) of an immunosuppressant (e.g., methotrexate, azathioprine, etc.) **within the last 6 months**; **AND**

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- ❑ Must be used as part of combination therapy with other agents; **AND**
- ❑ Member has a documented baseline physical exam and muscular strength/function prior to steroid and post-steroid. Baseline prior to IVIG. Dates taken (must be provided): _____

AND

- ❑ Serum creatine kinase (CK) levels and dates taken: (must be provided): _____

_____

❑ **Continuation of therapy for Dermatomyositis/Polymyositis. Progress notes/lab assessments must be submitted**

- ❑ Muscle biopsy documents normal **(IVIG DISCONTINUE)**
- ❑ Muscle biopsy documents Dermatomyositis/Polymyositis improving **(Approval - 6 months)**
- ❑ Muscle biopsy documents no improvement with IVIG post-6 months **(IVIG DISCONTINUE)**
- ❑ Muscular strength/function improvement. Dates taken: _____
- ❑ Serum creatine kinase (CK) levels and dates taken: (must be provided): _____

_____

❑ **Diagnosis - Fetal Alloimmune Thrombocytopenia (FAIT).**
Authorized Approval until delivery; Cannot be renewed. (Dose: 1g/kg weekly until delivery)

- ❑ Previous FAIT pregnancy; **OR**
- ❑ Family history of the disease; **OR**
- ❑ Screening reveals platelet alloantibodies

❑ **Diagnosis - Neonatal Alloimmune Thrombocytopenia (NAIT).**
Authorized Approval – One month (1 course) Only; Cannot be renewed.

❑ **Diagnosis - Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL).**
Authorized Approval - 4 months (Dose: 400mg/kg every 3-4 weeks)

- ❑ Used for prevention of infection; **AND**
- ❑ Member's IgG level is < 400 mg/dL

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❑ **Diagnosis - Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia (CLL)† OR Multiple Myeloma (MM)‡**
Authorized Approval - 6 months (Dose: 400mg/kg every 3-4 weeks)

- ❑ Member's IgG level is < 200 mg/dL **OR** both of the following:
  - ❑ Member has history of multiple hard to treat infections as indicated by at least **one of the following**:
    - ❑ Four or more ear infections within 1 year
    - ❑ Two or more serious sinus infections within 1 year
    - ❑ Two or more months of antibiotics with little effect
    - ❑ Two or more pneumonias within 1 year
    - ❑ Recurrent or deep skin abscesses
    - ❑ Need for intravenous antibiotics to clear infections
    - ❑ Two or more deep-seated infections including septicemia

    AND
  - ❑ Member has a deficiency in producing antibodies in response to vaccinations

    AND
- ❑ Titers were drawn before challenging with vaccination; **AND**
- ❑ Titers were drawn between 4 and 8 weeks of vaccination

❑ **Diagnosis - Relapsing-Remitting Multiple Sclerosis***

- ❑ Clinical records, labs, x-rays, etc. supporting the diagnosis of RRMS must be provided.
- ❑ Current medications and treatment plan with initiation of IVIG, including use of IVIG as monotherapy
- ❑ Initiation of immunosuppressive treatment, if necessary

❑ **Diagnosis - Kawasaki Syndrome (Pediatric Patients).**
Authorized Approval – 1 month; Cannot be renewed. (Dose: 1g/kg to 2g/kg, one course).

- ❑ Date of initial onset of symptoms: _____

  AND
- ❑ Current medications and treatment plan with initiation of IVIG: _____
  _____

❑ **Diagnosis - Allogeneic Bone Marrow or Stem Cell Transplant.**
Authorized Approval - 6 months (Dose: 500 mg/kg once weekly x 90 days, then 500 mg/kg every 3-4 weeks)

- ❑ Used for prevention of acute Graft-Versus-Host-Disease (aGVHD) or infection; **AND**
- ❑ Member's BMT was allogeneic; **AND**
- ❑ Member's IgG level is less than 400 mg/dL

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- ❑ **Diagnosis - Hyperbilirubinemia in the newborn**

- ❑ **Diagnosis - Guillain-Barre Syndrome. For ONE (1) treatment.**
  If another treatment is warranted, PA must be resubmitted.
  Maximum of 2 treatments. (Initial Dose: 2g/kg divided over 5 days, 2 courses)
  - ❑ Defined by the following:
    - ❑ Bilateral & flaccid weakness of the limbs; **AND**
    - ❑ Decreased or absent deep tendon reflexes in weak limbs; **AND**
    - ❑ Monophasic illness pattern and interval between onset and nadir of weakness between 12h and 28 days and subsequent clinical plateau; **AND**
    - ❑ Electrophysiological findings consistent with GBS; **AND**
    - ❑ Cytoalbuminologic dissociation (elevation of CSF protein level above laboratory normal value &/or CSF total white count <50 cells/µL; **AND**
    - ❑ Member is non-ambulatory and 4 weeks or less have elapsed since onset of symptoms

- ❑ **Diagnosis - HIV Infection/children.**
  Approval – 4 months. (Dose: 400 mg/kg every 2-4 weeks)
  - ❑ In conjunction w/ AZT or other antiretroviral, to prevent mild to severe bacterial infection w/CD4+ counts < 200/uL
  - ❑ In conjunction w/ AZT, to prevent maternal transmission of HIV infection
  - ❑ HIV-positive children exposed to measles or live in a high-prevalence measles area
  - ❑ HIV-related ITP

- ❑ **Diagnosis - Stiff-Person Syndrome.**
  Approval - 6 months (Dose: 2g/kg divided over 5 days, 28-days)
  - ❑ Member has anti-glutamic acid decarboxylase (GAD) antibodies; **AND**
  - ❑ Member failed at least 2 of the following treatments **within the last 9 months** from request of diagnosis: benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam; **AND**
  - ❑ Member has documented baseline on physical exam

  - ❑ **Reauthorization for Stiff-Person Syndrome:**
    - ❑ Positive anti-glutamic acid decarboxylase antibodies; **AND**
    - ❑ Baseline physical exam document improvement: member must meet **one** of the criteria below:
      - ❑ **Negative signs** – discontinue IVIG

        OR

      - ❑ **Positive signs** – continue and **TAPER** down IVIG

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- ❑ **Diagnosis - Toxic Shock Syndrome.**
  Approval – 4 months; Cannot be renewed (Dose: 2g/kg divided over 5 days, **one course)**
  - ❑ Infection is refractory to aggressive treatment. Include therapies tried.
  - ❑ Presence of an undrainable focus
  - ❑ Persistent oliguria with pulmonary edema

Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee:** ~~10/28/2008;~~ **11/20/2025**
REVISED/UPDATED: ~~2/04/2010; 6/14/2011; 8/19/2011; 4/19/2012; 10/1/2012; 7/8/2013; 1/15/2014; 4/7/2014; 8/13/2014; 10/31/2014; 8/10/2015; 9/30/2015; 12/30/2015; 1/29/2016; 8/18/2016; 9/22/2016; 12/11/2016; 7/27/2017; 5/21/2018; 12/31/2018; (Reformatted) 3/16/2019; 6/19/2019; 7/26/2019; 9/22/2019; 10/7/2019; 04/24/2024;~~ **(Reformatted) 12/12/2025**