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: Intravenous Immune Globulin (IVIG) (Medical)
[Primary Immunodeficiency Disorder]

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)**	❑ **Gammaplex®** [Immune Globulin Intravenous (Human) Liquid] **(J1557)**
❑ **Gammagard® Liquid** [Immune Globulin Infusion (Human), 10% Solution] **(J1569)**	❑ **Gamunex®-C** [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] **(J1561)**
❑ **Gammagard Liquid® ERC** [Immune Globulin Infusion (Human), 10% solution] **(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	
❑ **Alyglo™** [Immune Globulin Intravenous, Human-stwk] **(JI552)**	❑ **Qivigy** [Immune Globulin Intravenous, Human - kthm), 10% Solution] **(JI577)**
❑ **Asceniv** [Immune Globulin Intravenous (Human) – slra 10% Liquid] **(JI554)**	❑ **Yimmugo®** (Immune Globulin Intravenous, Human-dira), 10% Liquid **(JI553)**
❑ **Panzyga®** [Immune Globulin Intravenous (Human) – ifas 10% Liquid Preparation] **(J1576)**	

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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 #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code:** _____

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

❑ 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.

NOTE: Dosing should be calculated using adjusted body weight if the patient's actual body weight is 20% higher than his or her ideal body weight (IBW). ***IMPORTANT*** - If recommended adjusted body weight is not accepted, only **PARTIAL** approval will be granted.

- 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)]

CLINICAL CRITERIA: 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.

Initial Authorization: 6 months

❑ Severe combined immunodeficiency	❑ X-linked or autosomal recessive agammaglobulinemia
❑ Common variable immunodeficiency	❑ Wiskott-Aldrich syndrome
❑ CD40 ligand deficiency (X-linked hyper-IgM syndrome)	❑ Nuclear factor of κβ essential modifier deficiency
❑ Ataxia-telangiectasia	❑ DiGeorge Syndrome

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- ❑ Is this member switching from SQ to IVIG for Primary Immunodeficiency? ❑ Yes ❑ No

AND

- ❑ Provider has submitted number of hospital/ER visits required for hard-to-treat infections (e.g., recurrent ear infections, sinus infection, pneumonia, deep skin abscess, deep seated infections) in the last 12 months:

  _____

AND

- ❑ Provider has submitted number of antibiotics prescribed for hard-to-treat infections (e.g., recurrent ear infections, sinus infection, pneumonia, deep skin abscess, deep seated infections) in the last 12 months:

  _____

AND

- ❑ Member's IgG level is <200 mg/dL **(submit documentation)**

AND

- ❑ Member has a history of multiple hard to treat infections as indicated by at least **TWO** 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 vaccination

AND

- ❑ Titers were drawn before challenging with vaccination

AND

- ❑ Titers were drawn between 4 and 8 weeks of vaccination

AND

- ❑ **For Alyglo™, Panzyga®, Qivigy & Yimmugo® Requests**: Member must have a 90-day trial & failure of **three (3)** preferred IVIG products **(documentation of treatment failure must be submitted with request)**

AND

- ❑ **For Asceniv® Requests**: Member must have a 90-day trial & failure of **ALL** preferred IVIG products **(documentation of treatment failure must be submitted with request)**

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Reauthorization (Maintenance Therapy): 12 months for titrated doses. Doses above 1g/kg would be approved based on recent ER/hospital visits PLUS IVIG < 200 mg/kg within the last 3 months.

Reauthorization (High Maintenance Therapy): 3 months only. 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.

NOTE: 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 as long as immunoglobulin levels are maintained in the appropriate range).

- ❑ Member has experienced disease response as evidenced by at least **ONE** of the following:
  - ❑ Decrease in the frequency of infection
  - ❑ Decrease in the severity of infection

AND

- ❑ Number of hospital/ER admissions for hard-to-treat infections has **NOT** increased from baseline since beginning starting IVIG therapy

AND

- ❑ IgG level obtained within the last 30 days was therapeutic: 500-1200 mg/dL **(submit documentation)**

AND

- ❑ IgG trough levels >1250 mg/dL warrants IgG dose decrease. Has physician considered decreasing the IVIG dose? If not, please provider rationale for continued use of initial dose:

_____

_____

_____

_____

_____

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Medication being provided by: Please check applicable box below.

- ❑ **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.****