

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.

Immune Globulin SQ [Primary Immunodeficiency Disorder] (Medical)

Drug Requested: Check applicable box below. If not checked, authorization could be delayed.

- | | |
|--|--|
| <input type="checkbox"/> Cutaquiq® [Immune Globulin Subcutaneous (Human) – hipp, 16.5% solution] (J1555) | <input type="checkbox"/> Cuvitru® [Immune Globulin Subcutaneous (Human) 20% solution] (J1555) |
| <input type="checkbox"/> Gammagard® [Immune Globulin Infusion (Human)] (J1569) | <input type="checkbox"/> Gamunex-C® [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] (J1561) |
| <input type="checkbox"/> Hizentra® [Immune Globulin Subcutaneous (Human) 20% liquid] (J1559) | <input type="checkbox"/> Hyqvia® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] (J1575) (AG)* |
| <input type="checkbox"/> Xembify® [Immune Globulin Subcutaneous (Human) – klhw 20%] (J1558) | |

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: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

(Continued on next page)

- ☐ 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 a **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. **Check the diagnosis below that applies.**

Initial Authorization: 6 months

<input type="checkbox"/> Severe combined immunodeficiency	<input type="checkbox"/> X-linked or autosomal recessive agammaglobulinemia
<input type="checkbox"/> Common variable immunodeficiency	<input type="checkbox"/> Wiskott-Aldrich syndrome
<input type="checkbox"/> CD40 ligand deficiency (X-linked hyper-IgM syndrome)	<input type="checkbox"/> Nuclear factor of $\kappa\beta$ essential modifier deficiency
<input type="checkbox"/> Ataxia-telangiectasia	<input type="checkbox"/> DiGeorge Syndrome

- ☐ Is this member switching from IV to SQ IG for Primary immunodeficiency? ☐ Yes ☐ No

AND

- ☐ For Hyqvia requests: Member must be ≥ 18 years of age

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

(Continued on next page)

- ☐ 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

Reauthorization (Maintenance Therapy): 12 months for titrated doses considered by MagellanRx. 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 IVIG therapy

AND

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

AND

(Continued on next page)

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

Medication being provided by: Please check applicable box below.

- ☐ Location/site of drug administration: _____
NPI or DEA # of administering location: _____

OR

- ☐ Specialty Pharmacy – PropriumRx

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.****