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) (immunodeficiency) {Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)}

Drug Requested: Check applicable box below. If not checked, authorization could be delayed.	
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	
❑ **Hyqvia®** [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] **(J1575) (AG)***	❑ **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, if applicable:** _____

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.

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).

(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).

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.

Length of Authorization: Initial coverage will be provided for 12 months and may be renewed annually thereafter

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- ❑ Member is 18 years of age or older
- ❑ Prescribed by or in consultation with a specialist for CIDP
- ❑ Member has progressive or relapsing and remitting CIDP for > 2 months **(submit documentation)**
- ❑ Member was determined to have Probable or Definite CIDP according to EFNS/PNS 2010
- ❑ Member has decreased or absent deep tendon reflexes in upper or lower limbs
- ❑ Electrodiagnostic testing indicating demyelination must meet **TWO** of the following:
  - ❑ Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve
  - ❑ Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve
  - ❑ Abnormal temporal dispersion conduction must be present in at least 2 motor nerves
  - ❑ Reduced motor conduction velocity in at least 2 motor nerves
  - ❑ Prolonged distal motor latency in at least 2 motor nerves
  - ❑ Absent F wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve
  - ❑ Prolonged F wave latency in at least 2 motor nerves
  - ❑ ≥30% amplitude reduction of the proximal negative peak CMAP relative to distal, excluding the posterior tibial nerve, if distal negative peak CMAP≥20% of LLN, in two nerves, or in one nerve + ≥1 other demyelinating parameter in ≥1 other nerve
- ❑ Member has a baseline CIDP Disease Activity Status (CDAS) score ≥ 2 **(submit documentation)**
- ❑ Members baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength **(submit documentation)**
- ❑ Requested medication will **NOT** be used as maintenance therapy in combination with immunoglobulin or intravenous efgartigimod
- ❑ Members must have tried and failed at least **ONE** corticosteroid for at least 3 months **unless** member has a contraindication or intolerance to the use of corticosteroids **(failure is defined objective measurement such as INCAT score did not show improvement while on a steroid)**

  - ❑ Has member tried and failed a corticosteroid (e.g., oral prednisolone, IV methylprednisolone) for at least 3 months? ❑ Yes ❑ No

    If **YES**, provide the following information:

    Drug Name/Form: _____

    Strength: _____ Length of Therapy: _____

    Dosing Schedule: _____

  - ❑ Does member have any contraindications or intolerances to corticosteroids? ❑ Yes ❑ No

    If **YES**, please provide details: _____

    _____

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

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:** ~~7/21/2016; 5/23/2024; 11/20/2025;~~ **3/26/2026**
REVISED/UPDATED/REFORMATTED: ~~9/22/2016; 12/11/2016; 6/8/2017; 7/24/2017; 5/18/2018; 8/23/2018; 9/26/2018; 12/31/2018; 3/31/2019; 4/9/2019; 7/26/2019; 9/22/2019; 6/5/2024; 12/05/2025;~~ **4/16/2026**