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) - (Multifocal Motor Neuropathy - MMN) (Medical)

Drug Requested: Check applicable box below. If not checked, authorization could be delayed.	
❑ **Bivigam®** [Immune Globulin Intravenous (Human), 10% Liquid] **(J1556)**	❑ **Gammaked™** [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] **(J1561)**
❑ **Carimune® NF** [Nanofiltered, Immune Globulin Intravenous (Human)] **(J1566)**	❑ **Gamunex®-C** [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] **(J1561)**
❑ **Flebogamma® DIF** [Human Normal Immunoglobulin (IVIg)] **(J1572)**	❑ **Octagam®** [Immune Globulin Intravenous (Human) liquid preparation] **(J1568)**
❑ **Gammagard® Liquid** [Immune Globulin Infusion (Human), 10% Solution, for intravenous and subcutaneous administration] **(J1569)**	❑ **Panzyga®** [Immune Globulin Intravenous (Human) – ifas 10% Liquid Preparation] **(J1576)**
❑ **Gammagard® S/D** [Immune Globulin Intravenous (Human) Solvent/Detergent Treated (Freeze-Dried Concentrate)] **(J1556)**	❑ **Privigen®** [Immune Globulin Intravenous (Human), 10% Liquid] **(J1459)**

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 #: _____

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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:** _____

Weight: _____ **Date:** _____

Height: _____ **inches**

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).

❑ 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: 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 - 4 weeks only (Dose: Up to 2g/kg divided over 5 days in 28-day cycle)

- ❑ A baseline assessment of member's strength/weakness by a clinical measuring tool **[e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.] must** be submitted; **AND**
- ❑ Member must have progressive, symptomatic multifocal motor neuropathy (MMN) characterized by limb weakness; **AND**
- ❑ Nerve conduction study must be submitted to confirm that a demyelinating neuropathy is present **(conduction block, slowing, or abnormal temporal dispersion)** in at least two (2) nerves; **AND**
- ❑ Labs documenting that GM-1 antibody titers are elevated **must** be submitted

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Continued 6-month approval of IVIG after initial 4-week trial may be authorized when the following criteria are met:

- ❑ Member demonstrated a clinical response to therapy based on improvement from baseline score of the objective clinical measuring tool [e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.] used in the initial assessment **(submit assessment that was completed after 4-week initial therapy trial); AND**
- ❑ IVIG dose has been tapered down to lowest effective dose since initial approval

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

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

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:** 4/15/2013
REVISED/UPDATED/REFORMATTED: ~~6/30/2013; 8/19/2014; 10/31/2014; 5/23/2015; 12/30/2015; 1/29/2016; 8/18/2016; 9/22/2016; 12/11/2016; 7/24/2017; 5/21/2018; 12/31/2018; 3/17/2019; 9/22/2019;~~ **4/23/2024**