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.	
❑ **Bivigam®** [Immune Globulin Intravenous (Human), 10% Liquid] **(J1556)**	❑ **Gamunex®-C** [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] **(J1561)**
❑ **Carimune® NF** [Nanofiltered, Immune Globulin Intravenous (Human)] **(J1566)**	❑ **Hyqvia®** [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] **(J1575) (AG)***
❑ **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)**
❑ **Gammaked™** [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] **(J1561)**	

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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:** _____

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: _____ **Height:** _____

Date: _____

❑ 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.

Initial Authorization: 6 months

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- ❑ Progressive or relapsing motor and/or sensory symptoms of more than one limb **AND** hyporeflexia or areflexia in affected limbs present for at least 2 months;

AND

- ❑ Electrophysiologic findings indicate demyelinating neuropathy **(3 of the following 4 criteria are met per the American Academy of Neurology)**:
  - ❑ Partial conduction block* of ≥ 1 motor nerve;

OR

  - ❑ Reduced conduction velocity* of ≥ 2 motor nerves;

OR

  - ❑ Prolonged F-wave latencies* of ≥ 2 motor nerves or the absence of F-waves;

OR

  - ❑ Other causes of demyelinating neuropathy have been excluded (from the European Federation of Neurological Societies and the Peripheral Nerve Society):
    - ❑ Borrelia burgdorferi infection (Lyme disease), diphtheria, drug or toxin exposure probably to have caused the neuropathy;

OR

    - ❑ Hereditary demyelinating neuropathy;

OR

    - ❑ Prominent sphincter disturbance;

OR

  - ❑ Diagnosis of multifocal motor neuropathy;

OR

  - ❑ IgM monoclonal gammopathy with high titre antibodies to myelin-associated glycoprotein;

OR

  - ❑ Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, diabetic and non-diabetic lumbosacral radiculoplexus neuropathy, PNS lymphoma and amyloidosis.

(*- Definitions from the American Academy of Neurology)

AND

- ❑ Testing to support diagnosis should be provided. This includes, but is not limited to, the following:
  - ❑ Cerebrospinal fluid (CSF) examination demonstrating elevated CSF protein with leukocyte count $<10/mm^3$;
  - ❑ MRI showing gadolinium enhancement and/or hypertrophy of the cauda equina, lumbosacral or cervical nerve roots, or the brachial or lumbosacral plexuses

AND

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- ❑ Provide the member's baseline condition (before **ANY** treatment) using **one** of the following objective measurements:
  - ❑ Inflammatory neuropathy cause and treatment group (INCAT) sensory sum score

    OR
  - ❑ Assessment of grip strength via a hand-held dynamometer (e.g., Jamar, Vigorimerter)

    OR
  - ❑ Medical Research Council (MRC) scales or other similar, validated neurological scale

AND

- ❑ Recipients must have tried **(for at least 3 months)** and failed at least **one** corticosteroid **OR** has a contraindication or intolerance to the use of corticosteroids **(FAILED defined objective measurement such as INCAT score did not show improvement while on a steroid).**

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

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

    Drug Name/Form: _____

    Strength: _____ Length of Therapy: _____

    Dosing Schedule: _____

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

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

    _____

Reauthorization: 12 months, if diagnosis is still present. Significant improvement in clinical condition has been documented by an objective measurement such as the inflammatory neuropathy cause and treatment group (INCAT) sensory sum score; assessment of grip strength via a hand-held dynamometer (e.g., Jamar, Vigorimeter); or Medical Research Council (MRC) scales or other similar, validated neurological scales AND, when applicable, a reduction in the level of sensory loss should be noted.

- **Check below ALL that apply:**
  - ❑ For long-term treatment, evidence that the dose has been periodically reduced or the treatment withdrawn, and the effects measured

AND

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- ❑ **ONE** of the following measurements would show improvement (the same assessment must be used with baseline assessment). Denial would define no change or worsening.
  - ❑ Inflammatory neuropathy cause and treatment group (INCAT) sensory sum score

    OR
  - ❑ Assessment of grip strength via a hand-held dynamometer (e.g., Jamar, Vigorimerter)

    OR
  - ❑ Medical Research Council (MRC) scales or other similar, validated neurological scale

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:** ~~7/21/2016;~~ **5/23/2024**
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**