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) (Medical)**
(Miscellaneous Sjögren's Syndrome Neuropathies)

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**

❑ 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.

***IMPORTANT* - If recommended adjusted body weight is not accepted, a PARTIAL approval will be granted.**

Dosing should be calculated using adjusted body weight if the member'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)]

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/DIAGNOSIS: 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.

❑ **Diagnosis: Small Fiber Sensory Neuropathy associated with Sjögren's Syndrome**

Initial Authorization: 6 months (Dose: 2 g/kg/month)

❑ Member has tried and failed at least **TWO** of the following first-line therapies for a minimum of 3 months due to toxicity OR failure to stabilize disease. **Submit supporting document on toxicities and progression**. **Check ALL that apply (include drug name, dose, duration):**

- ❑ Tricyclic antidepressant _____
- ❑ SNRI _____
- ❑ Anticonvulsant _____
- ❑ Topical lidocaine_____

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- ❑ Diagnosis based on American-European Consensus Group Criteria (presence of 4 out of 6 items if histopathology or autoantibodies positive **OR THREE (3)** of the following are positive: ocular signs, histopathology, salivary gland involvement, autoantibodies):
  - ❑ Ocular symptoms (**at least 1**):
    - ❑ Daily, persistent, troublesome dry eyes for more than 3 months
    - ❑ Recurrent sensation of sand or gravel in eyes
    - ❑ Use of tear substitutes more than 3 times a day
  - ❑ Oral symptoms (**at least 1**):
    - ❑ Daily feeling of dry mouth for more than 3 months
    - ❑ Recurrent or persistent swollen salivary glands
    - ❑ Frequently drink liquids to aid in swallowing dry food
  - ❑ Ocular signs (**at least 1**):
    - ❑ Schirmer's I test without anesthesia (≤ 5 mm in 5 minutes)
    - ❑ Rose Bengal score or other ocular dry eye score (≥ 4 with van Bijsterveld's scoring)
  - ❑ Histopathology: In minor salivary glands (obtained through normal-appearing mucosa) focal lymphocytic sialadenitis, evaluated by an expert histopathologist, with a focus score ≥ 1, defined as several lymphocytic foci (which are adjacent to normal-appearing mucous acini and contain more than 50 lymphocytes) per 4 mm^2 of glandular tissue
  - ❑ Salivary gland involvement (**at least 1**):
    - ❑ Unstimulated whole salivary flow (≤ 1.5 mL in 15 minutes)
    - ❑ Parotid sialography showing presence of diffuse sialectasis without evidence of obstruction in major ducts
    - ❑ Salivary scintigraphy showing delayed uptake, reduced concentration and/or delayed excretion of tracer
  - ❑ Autoantibodies present (Ro or SSA, La or SSB, or both)
- ❑ Confirmed small fiber neuropathy by skin biopsy from distal leg
- ❑ Baseline pain and disability score documentation has been submitted:
  - ❑ Baseline Visual Analogue Scale (VAS): _____
  - ❑ Baseline Modified Rankin Scale (MRS): _____

❑ **Diagnosis: Small Fiber Sensory Neuropathy associated with Sjögren's Syndrome**
Reauthorization: 12 months (Dose: 0.4 g/kg/month)

- ❑ Member demonstrated a clinical response to therapy based on improvement from baseline score of the objective clinical measuring tool VAS or MRS
- ❑ IVIG dose has been tapered down to lowest effective dose since initial approval

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❑ Diagnosis: Other Peripheral Neuropathies associated with Sjögren's Syndrome

Initial Authorization: 6 months (Dose: 2 g/kg/month)

- ❑ Diagnosis based on American-European Consensus Group Criteria (presence of 4 out of 6 items if histopathology or autoantibodies positive) **OR THREE (3)** of the following are positive: ocular signs, histopathology, salivary gland involvement, autoantibodies):
  - ❑ Ocular symptoms (**at least 1**):
    - ❑ Daily, persistent, troublesome dry eyes for more than 3 months
    - ❑ Recurrent sensation of sand or gravel in eyes
    - ❑ Use of tear substitutes more than 3 times a day
  - ❑ Oral symptoms (**at least 1**):
    - ❑ Daily feeling of dry mouth for more than 3 months
    - ❑ Recurrent or persistent swollen salivary glands
    - ❑ Frequently drink liquids to aid in swallowing dry food
  - ❑ Ocular signs (**at least 1**):
    - ❑ Schirmer's I test without anesthesia (≤ 5 mm in 5 minutes)
    - ❑ Rose Bengal score or other ocular dry eye score (≥ 4 with van Bijsterveld's scoring)
  - ❑ Histopathology: In minor salivary glands (obtained through normal-appearing mucosa) focal lymphocytic sialadenitis, evaluated by an expert histopathologist, with a focus score ≥ 1, defined as several lymphocytic foci (which are adjacent to normal-appearing mucous acini and contain more than 50 lymphocytes) per 4 mm^2 of glandular tissue
  - ❑ Salivary gland involvement (**at least 1**):
    - ❑ Unstimulated whole salivary flow (≤ 1.5 mL in 15 minutes)
    - ❑ Parotid sialography showing presence of diffuse sialectasis without evidence of obstruction in major ducts
    - ❑ Salivary scintigraphy showing delayed uptake, reduced concentration and/or delayed excretion of tracer
  - ❑ Autoantibodies present (Ro or SSA, La or SSB, or both)
- ❑ Peripheral neuropathy confirmed by electromyography
  - ❑ Sensorimotor
  - ❑ Sensory ataxic neuropathy (ganglionopathy)
  - ❑ Nonataxic sensory polyneuropathy
- ❑ Baseline pain and disability score documentation has been submitted:
  - ❑ Baseline Visual Analogue Scale (VAS): _____
  - ❑ Baseline Modified Rankin Scale (MRS): _____

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❑ **Diagnosis: Other Peripheral Neuropathies associated with Sjögren's Syndrome**
Reauthorization: 12 months (Dose: 0.4 g/kg/month)

- ❑ Member demonstrated a clinical response to therapy based on improvement from baseline score of the objective clinical measuring tool VAS or MRS
- ❑ 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:** 5/19/2022
REVISED/UPDATED/REFORMATTED: ~~5/27/2022; 6/13/2022; 6/17/2022;~~ **4/23/2024**