

Hospital Taiping Human Normal Immunoglobulin (IVIG) Request Form IVIG/HTPG/2022

Patient Name:		Ward/Clinic:	
RN Number:		Age:	
IC Number:		Gender:	Male/Female

ALL FIELDS BELOW ARE MANDATORY

SECTION A: Physician Information

Name of Ordering Physician (Stamp & Signature):		Verified by HOD (Stamp & Signature): <small>Not required for approved request</small>	
Date requested:		Is the patient seen by visiting consultant? Yes/No	
Date required:		If yes, please state the name of consultant: _____	

SECTION B: Request Type

<input type="checkbox"/> Initial request: Maximum 6 months approval	
<input type="checkbox"/> Approved request: Stamp and signature of HOD is not required	
<input type="checkbox"/> Renewal request: A reassessment should be done to confirm IG treatment continues to be effective and that minimum effective dose is being applied. Maximum 12 month approval.	

SECTION C: Clinical Indications

Adults
<input type="checkbox"/> Primary hypogammaglobulinaemia and other deficiency states <input type="checkbox"/> Severe refractory ITP (platelet less than 20,000) with internal bleeding, particularly central nervous system (Platelet count= _____) <input type="checkbox"/> Septicaemia in immunocompromised patients or patients not responding to antibiotics <input type="checkbox"/> Chronic lymphocytic leukaemia not responding to conventional therapy <input type="checkbox"/> Guillain-Barré Syndrome/Acute inflammatory demyelinating polyneuropathy <input type="checkbox"/> Myasthenia gravis <input type="checkbox"/> Chronic inflammatory demyelinating polyneuropathy <input type="checkbox"/> Multifocal motor neuropathy <input type="checkbox"/> Systemic lupus erythematosus
Paediatrics
<input type="checkbox"/> Kawasaki disease <input type="checkbox"/> Immune thrombocytopenia / Idiopathic thrombocytopenic purpura (Platelet count= _____) <input type="checkbox"/> Guillain-Barré Syndrome <input type="checkbox"/> Neonatal jaundice secondary to isoimmune hemolytic disease of newborn <input type="checkbox"/> Neonatal alloimmune thrombocytopenia <input type="checkbox"/> Neonate of mother with immune thrombocytopenia
<input type="checkbox"/> Other (please specify diagnosis): _____ <small>This request will require screening by the IVIG Use Advisory Panel. Please include information regarding treatment to date and documentation to support IG treatment for an unapproved indication.</small>
Justifications: <small>Refer to diagnostic criteria in the next page & specify its fulfilment (kindly attach documents to support)</small>

SECTION D: Dosage Information

****Dose must be adjusted for BMI greater than or equal to 30kg/m²**

Weight: _____ kg Height: _____ cm BMI: _____ kg/m² Adjusted body weight: _____ kg

<input type="checkbox"/> Induction / One-time dose	_____ g/kg = Total dose _____ G	Frequency: _____	over _____ days
<input type="checkbox"/> Maintenance dose	_____ g/kg = Total dose _____ G	Frequency: _____	over _____ days
	Duration: _____ months		

SECTION E: For Pharmacy Use

<input type="checkbox"/> Dose verified	<input type="checkbox"/> Dose adjusted to: G	Signature:
<input type="checkbox"/> Confirmed with IVIG Use Advisory Panel	<input type="checkbox"/> Denied	Date:
<input type="checkbox"/> INTRAGRAM®	<input type="checkbox"/> FLEBOGAMMA®	
<input type="checkbox"/> Others:		

Diagnostic criteria for IVIG use based on guidelines

Hypogammaglobulinemia and other deficiency state

Subjective: •Positive family history •Infections in multiple anatomic locations •Increasing frequency and severity of infections with age	Laboratory: •Lymphopenia (absolute lymphocyte count <3000 per mm ³ in newborn) or neutropenia (absolute neutrophil count <1500 per mm ³) on FBC ¹ •Low immunoglobulin levels •T & B cells enumeration test showing absent or low T/ B cells •Specific genetic test to detect the disease
Objective: •Recurrent serious infections with common pathogens •Serious infections with unusual pathogens	Criteria for IVIG use: •For replacement of immunoglobulin

Idiopathic thrombocytopenia purpura (ITP)

Subjective: •Patient presents with symptoms of bleeding (purpura, menorrhagia, epistaxis, gingival bleeding, bruising tendency) •Exclude risk factors systemic symptoms link to other illnesses or to medications (heparin, alcohol, quinidine, quinine, sulfonamides)	Laboratory: •Thrombocytopenia needs to be confirmed on peripheral blood film examination to exclude pseudo-thrombocytopenia. •An autoimmune screen should be carried out to exclude other autoimmune diseases which may be associated with thrombocytopenia, e.g. systemic lupus erythematosus or antiphospholipid syndrome. HIV antibody testing should also be done in patients with risk factors for HIV infection
Objective: •Signs of bleeding (purpura, non-palpable petechiae, haemorrhagic bullae on mucuous membrane, retinal haemorrhage, per-rectal bleed, neurological symptoms that may suggest intracranial haemorrhage) •Non-palpable spleen	Criteria for IVIG use: •FBC: Platelet < 20,000 •Fast correction of platelet level is needed e.g. need to undergone surgery or life-threatening bleeding •Refractory to existing medication treatment •Contraindicated to first-line therapy

Septicaemia in immunocompromised patients

Subjective: •History suggestive of infection •Risk factor of immunocompromise (IVDU, alcoholics, neglected elderly, post chemotherapy)	Laboratory: •Elevated lactate (above upper limit of normal) •Creatinine >2mg/dL •Total Bilirubin >2mg/dL •Thrombocytopenia (platelet count<100,000) •Coagulopathy (INR>1.5)
Objective: •Septic shock (SBP <90mmHg, mean arterial pressure <70mmHg, decreases in SBP >40mmHg) •Decreased urine output (<0.5ml/kg/hour for more than 2 hours despite fluid resuscitation) •Clinical condition deteriorating despite on antibiotics •Acute lung injury/ARDS	Criteria for IVIG use: •Secondary immunodeficiency (HIV, malnutrition, post chemotherapy, transplant patient) who suffered severe infection with proven specific antibody failure (PSAF)* or serum IgG level <4g/l ³ * PSAF= failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines.

Chronic lymphocytic leukemia (CLL)

Subjective: •Weight loss, fever, night sweats, muscle wasting, mucocutaneous bleeding	Laboratory: •FBC showing absolute lymphocytosis •BMAT: Presence of more than or equal to 5 × 10 ⁹ /L B lymphocytes (5000/μL) in the peripheral blood for the duration of at least 3 months. The clonality of the circulating B lymphocytes needs to be confirmed by flow cytometry. •Immunophenotyping:CLL cells coexpress the T-cell antigen CD5 and B-cell surface antigens CD19, CD20, and CD23.
Objective: •Splenomegaly, hepatomegaly, petechiae, pallor	Criteria for IVIG use: •CLL with hypogammaglobulinaemia and/ or recurrent bacterial infections associated with B-cell CLL for prophylaxis against infections

Guillain-Barré Syndrome (GBS)

Subjective: •Progressive, relatively symmetrical weakness with decreased or absent myotatic reflexes; symptoms must reach maximal intensity within four weeks of onset and other possible causes must be excluded.	Laboratory: •Lumbar puncture showing cytoalbuminologic dissociation (elevation of CSF protein, >0.55 g/L without elevation in CSF white blood cells)
Objective: •Flaccid paralysis of limbs with absent reflexes	Criteria for IVIG use: •Once diagnosis has been confirmed

Myasthenia gravis

Subjective: •Body weakness worse during the end of the day	Laboratory: •Presence of antibodies to acetylcholine receptor (AChR) or MUSK
Objective: •Body weakness with fatigability •Positive ice pack test	Criteria for IVIG use: •Central involvement or impending respiratory distress (Myasthenia crisis) •Regardless of respiratory function indices, the need for mechanical ventilation is a sufficient criterion to define myasthenic crisis. ⁵

Chronic Inflammatory demyelinating neuropathy (CIDP)

Subjective: •Proximal or distal limb weakness for at least 2 months. •Sensory symptoms such as tingling and numbness of hands and feet.	Laboratory: •Lumbar puncture showing cytoalbuminologic dissociation (elevation of CSF protein, >0.55 g/L without elevation in CSF white blood cells) AND •Nerve conduction study showing peripheral nerve demyelination
Objective: •Symmetric, motor-predominant peripheral neuropathy that causes both proximal and distal weakness, sensory impairment that is usually greater for vibration and position sense than for pain and temperature sense, and areflexia. The course can be progressive or relapsing-remitting over at least 2 months.	Criteria for IVIG use: •Once diagnosis has been confirmed

Multifocal motor neuropathy

Subjective: •Weakness without objective sensory loss in the distribution of 2 or more nerves is present for more than 1 month.	Laboratory: •Definite motor conduction block is present in at least one motor nerve •Elevated titres of serum IgM anti-GM1 antibodies •Increased cerebrospinal fluid protein (<1g/L) •MRI shows increased signal on T2-weighted imaging of brachial plexus with diffuse nerve swelling
Objective: •Objective clinical improvement following intravenous immunoglobulin treatment	Criteria for IVIG use: •Once diagnosis has been confirmed

Systemic lupus erythematosus (SLE)

Subjective: •Malar rash •Fever •Weight loss •Seizure/ delirium/ psychosis •Non scarring alopecia	<ul style="list-style-type: none"> •Oral ulcers •Arthralgia/ Arthritis •Fatigue 	Laboratory: •Leukopenia •Autoimmune hemolysis •Renal biopsy class II/III/IV/V lupus nephritis •anti-cardiolipin antibodies/ anti B2GP1 antibodies/ lupus anticoagulant •Low C3 or Low C4/ Low C3 and Low C4 •Anti-dsDNA antibody or Anti-Smith antibody	•Thrombocytopenia •Proteinuria >0.5g/24H
Objective: •Pleural or pericardial effusion •Peripheral limb oedema •Lymphadenopathy •Jaundice/ pale	Criteria for IVIG use: •RPGN- proteinuria with or without RBC cast with rapid decline GFR of at least 50%, from few days- 3 months •Cerebral lupus- acute psychosis/ generalised seizure/ stroke like symptoms/ peripheral neuropathies •Serositis- pleuritis(pleural effusion/ pleurisy)/ pericarditis (chest pain typically less severe when sitting up, more severe when lying down or breathing deeply/ pericardial effusion/ ECG findings supporting pericarditis)		