



Australian Health
Ministers' Conference

IVIg Criteria **Revisions**

Last updated February 2009

February 2009

Medical condition**Primary immunodeficiency diseases with antibody deficiency**

Dose

Maintenance dose: 0.4g/kg every four weeks, modifying dose and/or schedule to achieve IgG trough level of at least the lower limit of the age-specific serum IgG reference range.

Loading dose: One additional dose of 0.4g/kg in the first month of therapy is permitted if the serum IgG level is markedly reduced.

Chronic suppurative lung disease: Dosing to achieve IgG trough level of up to 9g/L is permitted if chronic suppurative lung disease is not adequately controlled at an IgG trough level at the lower limit of the age-specific serum IgG reference range.

Subcutaneous administration of immunoglobulins (SCIG) is a suitable alternative to IVIg in this disease.

Refer to the current product information sheet for further information.

Medical
condition

Myasthenia Gravis

Dose

Maintenance: 0.4–1g/kg 4–6 weekly.

Induction or prior to surgery or during myasthenic crisis: 1–2g/kg in 2 to 5 divided doses.

Aim for **minimum dose** to maintain optimal functional status.

Note: Smaller dosage may be of greater efficacy.

Refer to the current product information sheet for further information.

Medical condition**Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)**

Exclusion criteria for IVIg therapy

Reversible underlying cause of hypogammaglobulinaemia.

The following conditions should not be approved under this indication:

1. Acquired hypogammaglobulinaemia secondary to haematological malignancies (see page 60);
2. Paediatric HIV infection (see page 195);
3. Transplantation related immunomodulation (HSCT and solid organ transplantation) (see pages 148, 160 and 206).

Review criteria for assessing the effectiveness of IVIg use

IVIg therapy for a maximum of **one** year with repeat immunological evaluation required prior to recommencement of IVIg. Cessation of IVIg to enable for this evaluation may be delayed until the next summer (after the first 12 months).

Medical
condition

Specific Antibody Deficiency

Review
criteria for
assessing the
effectiveness
of IVIg use

Specific Antibody Deficiency

- IVIg therapy for a maximum of one year with repeat immunological evaluation at least once to confirm a persistent specific antibody deficiency. An immunoglobulin washout period of 4 to 6 months allows accurate assessment of endogenous Ig. Treatment may be extended to allow assessment following the treatment cessation period to occur over summer. The patient who requalifies for IVIg under the current Criteria will be considered to have a persisting SAD diagnosis and will not require further treatment cessation to qualify for IVIg. Prophylactic antibiotics may be considered to cover the period of IVIg cessation.
- IgG trough levels are of no value in this setting

IgG subclass deficiency

New patients:

- Isolated abnormalities of IgG subclasses with normal serum IgG levels, with or without recurrent infection, do NOT meet current Criteria for IVIg in Australia. These patients should be assessed under the criteria for 'Specific Antibody Deficiency'.

Patients currently receiving IVIg:

- Who have not experienced ongoing bacterial susceptibility over the previous 12 months, or do not have bronchiectasis. These individuals will no longer qualify for ongoing IVIg supply. IVIg will cease. Patients can be reassessed at the discretion of their physician for endogenous antibody production and specific antibody responses after 4-6 months, and may subsequently requalify for IVIg under current Criteria according to the findings. Prophylactic antibiotics may be considered for the reassessment period.

**Medical
condition**

Specific Antibody Deficiency continued

Review
criteria for
assessing the
effectiveness
of IVIg use

- Who have demonstrated ongoing bacterial susceptibility over the previous 12 months, or clinically active bronchiectasis. These patients may continue to receive IVIg under the diagnosis of IgG subclass deficiency as the risk of IVIg cessation is unknown. Physicians are asked to consider cessation of IVIg over summer and re-evaluation of immune function, as there may be alternative causes for infectious susceptibility.
 - IgG trough levels are of no value in this setting.
 - Please also refer to FAQ 5a
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Condition	Level of evidence
Myocarditis in children	4a
There is some evidence that IVIg improves cardiac function in children with proven or likely viral myocarditis.	
Refer to current product information for further information	
References:	
Drucker NA, Colan SD, Lewis AB, et al. Gamma-globulin treatment of acute myocarditis in the pediatric population. <i>Circulation</i> 1994;89:252-7.	
Robinson J, Hartling L, Vandermeer B, et al. Intravenous immunoglobulin for presumed viral myocarditis in children and adults (Cochrane Review). In: <i>The Cochrane Library</i> , Issue 1, 2005. Chichester, UK. John Wiley & Sons, Ltd.	

Condition	Level of evidence
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Paraneoplastic neurological syndromes

4a

IVIg may be indicated in selected cases where treatment of the underlying disease has not led to an improvement in the neurologic syndrome, where other therapies are contraindicated or have failed, or if the neurologic features warrant urgent intervention.

This should be read to include multiple types of paraneoplastic cerebellar degeneration. Such cases will only have access to ongoing treatment with IVIg where there has been an objective measurable response.

Refer to current product information for further information**References:**

Darnell RB, Posner JB. Paraneoplastic syndromes involving the nervous system. *N Engl J Med* 2003;349(16):1543–54

Voltz R. Intravenous immunoglobulin therapy in paraneoplastic neurological syndromes. *J Neurol* 2006;253(Suppl 5):v33–v38.

Potassium channel antibody-associated encephalopathy

4a

Case reports of benefit from various therapies, including IVIg are reviewed by Vincent A et al: Potassium channel antibody-associated encephalopathy: a potentially immunotherapy-responsive form of limbic encephalitis.

Limbic encephalitis can include potassium channel antibody associated encephalopathy but if Hu antibodies are found to be present, treatment with IVIg is not indicated.

Refer to current product information for further information**References:**

Vincent A, Buckley C, Schott JM, et al. Potassium channel antibody-associated encephalopathy: a potentially immunotherapy-responsive form of limbic encephalitis. *Brain* 2004;127(Pt 3):701–12.