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The Ig Criteria have changed.

Criteria for clinical use of immunoglobulin in Australia (the Criteria)

Neurology Conditions - Summary of Criteria Changes

The *Criteria for clinical use of immunoglobulin in Australia* (Criteria) is under a continuous review cycle following release of Version 3 on 22 October 2018. The table below summarises subsequent changes made by medical condition and indication to the Criteria following the publication of Version 3. Changes will be applied immediately to new authorisations and to existing authorisations at the next continuing treatment request, unless otherwise stated. This table will be updated when any change is made.

Medical condition	Indication/s	Summary of changes	Date changed	Version number
Acute disseminated encephalomyelitis (ADEM)	• Monophasic ADEM unresponsive to corticosteroid therapy or where corticosteroids are contraindicated • Recurrent or multiphasic ADEM unresponsive to steroid therapy or where corticosteroid therapy has become intolerable or is contraindicated • Relapse of patients with recurrent or multiphasic ADEM within six months of commencement of trial off immunoglobulin therapy	• Up to two one off doses, in addition to the induction dose, are now permitted over the course of the authorisation in severely affected patients who are not responding to maintenance therapy. • The maintenance dose can now be requested as a divided dose in all indications.	March 2020	3.1

Medical condition	Indication/s	Summary of changes	Date changed	Version number
Autoimmune encephalitis mediated by antibodies targeting cell-surface antigens (AMAE)	• Confirmed antibody mediated autoimmune encephalitis (AMAE) or limbic encephalitis – cell surface antibody positive • Suspected antibody mediated autoimmune encephalitis (AMAE) – antibody results not available or sero-negative AMAE or seronegative limbic encephalitis	• The adapted Modified Rankin Scale (MRS) replaces the MRS; allowing prescribers to accurately provide a score where their patient's primary symptom is seizures. • The Qualifying Criteria post-script has been updated in suspected AMAE to clarify the appropriate indication for patients with anti-GAD, thyroid and the classical intracellular antineuronal antibodies.	March 2020	3.1
Childhood epileptic encephalopathy	• Children with epileptic encephalopathy resistant to anti-epileptic medications and steroid therapy or steroid responsive but dependent • Relapse of epileptic encephalopathy following a trial of weaning from Ig therapy in a patient previously demonstrating response	• The age limitation has been removed in BloodSTAR to allow adult patients approved as children to access ongoing Ig at review where clinically appropriate • Exclusion Criteria links have been updated • Correction of typographical errors in the qualifying postscript and review preamble • The Qualifying Preamble has been updated to extend the time limitation to access Ig following trial off therapy to six months	March 2020	3.2
Chronic inflammatory demyelinating polyneuropathy (CIDP), (including IgG and IgA paraproteinaemic demyelinating neuropathies)	• Treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) for patients in whom walking is compromised or there is significant disability • Relapse of chronic inflammatory demyelinating polyneuropathy (CIDP) patients within six months of commencement of trial off Ig therapy	• An additional one off dose is now available during the course of the authorisation in the form of intravenous immunoglobulin or subcutaneous immunoglobulin • Separate doses are now available for intravenous and subcutaneous immunoglobulin administration.	October 2019	3.2
		• Bibliography links have been corrected. • Data entry error has been corrected in the Qualifying Criteria for indication Relapse of chronic inflammatory demyelinating polyneuropathy (CIDP) patients within six months of commencement of trial off immunoglobulin therapy. • Subcutaneous administration of Ig can be considered as an alternative to intravenous Ig (IVIg) following stabilisation with IVIg.	August 2019	3.1

Medical condition	Indication/s	Summary of changes	Date changed	Version number
Guillain–Barré Syndrome (GBS)	• Initial therapy for GBS with significant disability and progression • Relapse in GBS treatment-related fluctuation with initial improvement and subsequent deterioration post IVIg treatment	• Intensivist added to list of specialists that can diagnose GBS, in addition to a Neurologist, Paediatrician or a General Medicine Physician. A second dose must still be on the advice of, and after assessment by, a neurologist.	March 2020	3.1
Inflammatory Myopathies: Inclusion Body Myositis (IBM)	• Patients with inclusion body myositis (IBM) who have dysphagia limiting dietary intake	• Maintenance dose text has been clarified	March 2020	3.1
Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and necrotising autoimmune myopathy (NAM)	• Treatment of significant muscle weakness or dysphagia unresponsive to corticosteroids and other immunosuppressant agents in adults with biopsy-proven PM or DM or NAM or children with clinical, biochemical and imaging abnormalities consistent with definite PM or DM or NAM	• Corticosteroids are now listed as one of the two immunosuppressant medications that can be trialled prior to Ig. • List order changed to most common order of trial.	March 2020	3.2
Opsoclonus-myoclonus ataxia (OMA)	• Treatment of OMA initially diagnosed in a child	• Data entry error corrected to remove age limitation in BloodSTAR.	May 2019	3.1
Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infections (PANDAS) or paediatric acute neuropsychiatric disorders (PANS)	• Relapse of paediatric autoimmune neuropsychiatric disorder associated with streptococcal infections (PANDAS) or paediatric acute neuropsychiatric disorders (PANS) symptoms within three months of commencement of trial off Ig therapy	• The Qualifying Preamble has been updated to extend the time limitation to access Ig following trial off therapy to six months.	March 2020	3.1
Susac syndrome	• Probable or definite Susac syndrome in concurrence with high dose corticosteroids	• Data entry error corrected in the Modified Rankin Scale controls for Review Criteria.	March 2020	3.1