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The Ig Criteria have changed.

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

Immunology 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
Anti-neutrophil cytoplasmic antibody (ANCA)	• Relapse in ANCA positive systemic necrotising vasculitis resistant following response to Ig therapy	• Correction of data entry to remove max dose restriction.	April 2019	3.1
Autoimmune congenital heart block	• Prevention of recurrent autoimmune congenital heart block where maternal SSB (La) and/or SSA (Ro) antibodies are present {not male}	• The gestational age qualifying values have been updated to allow therapy up until delivery.	March 2020	3.1

Medical condition	Indication/s	Summary of changes	Date changed	Version number
Kawasaki Disease	• Early Kawasaki disease to prevent coronary artery pathology	• A new evidence item has been introduced to capture whether the presentation of Kawasaki-like symptoms are linked to COVID-19, including confirmation by diagnostic tests for COVID-19. • The age limitation has been removed in BloodSTAR to allow young adults over the age of 18 years old to be diagnosed with Kawasaki disease.	July 2021	3.1
Primary immunodeficiency diseases (PID) with antibody deficiency	• Replacement therapy in common variable immune deficiency (CVID) – ESID diagnostic criteria met	• Reduce the age to 2 years (from 4 years) for indication 1 (replacement therapy in common variable immune deficiency).	November 2023	3.4

Medical condition	Indication/s	Summary of changes	Date changed	Version number
	• Replacement therapy in common variable immune deficiency (CVID) – ESID diagnostic criteria met • Replacement therapy in possible common variable immune deficiency (CVID) – (below normal serum IgG and normal IgA level) • Replacement therapy in transient hypogammaglobulinaemia of infancy (children aged less than 4 years) • Replacement therapy in recognised primary immunodeficiencies for which immunoglobulin replacement is universally indicated (e.g SCID, Wiskott-Aldrich syndrome, etc.)	• The interpretation of results values for all Ig levels now include provision to specify when results are above normal range. • The evidence item for 'Secondary hypogammaglobulinaemia has been excluded' has been removed from all indications as is included in exclusion criteria. • The trial cessation criterion wording in Review Criteria has been updated to clarify the need for it to be completed. • The Description and Diagnostic Criteria has been updated to provide clarity around the European Society for Immunodeficiency Diseases (ESID) diagnostic criteria. • The evidence item for switched memory B cells interpretation of results wording has been updated. • Where more than one immunoglobulin is tested on the same day, the date of test is now only required for the first immunoglobulin level. • The evidence items in Qualifying Criteria requiring the patient's age no longer require entry of the date of birth. • The Serum IgA evidence item in the Qualifying Criteria has been updated. • Where there is an option to record a review history of no infection, the requirement to enter a date has been removed.	March 2020	3.3

Medical condition	Indication/s	Summary of changes	Date changed	Version number
		• An additional one off dose is available during the course of the authorisation in the form of intravenous immunoglobulin or subcutaneous immunoglobulin. • Maintenance dose has been amended to 0.4 – 0.6g/kg every four weeks or more frequently. • Separate doses are now available for intravenous and subcutaneous immunoglobulin administration.	October 2019	3.2
Pyoderma Gangrenosum (PG)	• Relapse of PG in previously responding patients following a trial off Ig therapy	• Removal of the six month limitation to access Ig following trial off therapy.	March 2020	3.1
Secondary hypogammaglobulinaemia unrelated to Haematological malignancy or haemopoeitic stem cell transplant (HSCT)	• Replacement therapy for recurrent or severe bacterial infections or disseminated enterovirus infection associated with hypogammaglobulinaemia caused by a recognised disease process or B cell depletion therapy and/or immunosuppressant therapy.	• Change in clinical and authoriser instructions to allow a higher maintenance dose (up to 2g/kg/4 weeks) for chronic disseminated enterovirus infection. • Inclusion of fields to allow entry of IgG levels under the evidence item for "Serum IgG greater than 4g/L … and at least one life-threatening infection in the last 12 months"	November 2023	3.4
		• The trial cessation criterion wording in Review Criteria has been updated to clarify the need for it to be completed. • Where more than one immunoglobulin is tested on the same day, the date of test is now only required for the first immunoglobulin level. • The interpretation of results values for all Ig levels now include provision to specify when results are above normal range. • A bibliography link has been corrected.	March 2020	3.3

Medical condition	Indication/s	Summary of changes	Date changed	Version number
		• An additional one off dose is available during the course of the authorisation in the form of intravenous immunoglobulin or subcutaneous immunoglobulin. • Maintenance dose has been amended to 0.4 – 0.6g/kg every four weeks or more frequently. • Separate doses are now available for intravenous and subcutaneous immunoglobulin administration.	October 2019	3.2
Specific antibody deficiency	• Prevention of recurrent/persistent infections in individuals with a demonstrated failure to mount protective IgG antibody responses to vaccine antigen challenge, despite normal total serum IgG levels • Prevention of infection in individuals with proven specific antibody deficiency who have had a life-threatening infection or a series of serious infections following trial-off Ig therapy • Prevention of infection in patients currently receiving immunoglobulin therapy for a diagnosis of IgG subclass deficiency provided that a diagnosis of specific antibody deficiency is confirmed following cessation of immunoglobulin therapy	• The Qualifying Preamble has been updated to clarify the eligibility requirements.	March 2020	3.2
		• Separate doses are now available for intravenous and subcutaneous immunoglobulin administration.	October 2019	3.1