

***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) [Proteinase 3 (PR3) or myeloperoxidase (MPO)] - positive systemic necrotising vasculitis | * Anti-neutrophil cytoplasmic antibody (ANCA) positive systemic necrotising vasculitis failing to respond to corticosteroids and cytotoxic immunosuppression
* 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
* Maternal therapy for treatment of congenital heart block where maternal SSB (La) and/or SSA (Ro) antibodies are identified
* Post-natal treatment of congenital heart block where SSB (La) and/or SSA (Ro) are present
 | * Added information to indication 3 to clarify that this indication only applies to patients up to 6 months of age.
* Updated links for several references.
 | April 2025 | 3.2 |
| * The gestational age qualifying values have been updated to allow therapy up until delivery.
 | March 2020 | 3.1 |
| Inborn errors of immunity (IEI) with antibody deficiency  | * 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 inborn errors of immunity for which immunoglobulin replacement is universally indicated (e.g. SCID, Wiskott-Aldrich syndrome, etc.)
 | * Updated descriptive text to include more information about inborn errors of immunity.
* Amended the criteria for indication 4 to remove the requirement of hypogammaglobulinaemia in patients with recognised inborn errors of immunity for which immunoglobulin replacement is universally indicated.
* Added four new references relating to the changes to indication 4.
* Updated links for several references.
* Added links to exclusion criteria.
 | April 2025 | 3.6 |
| * Changed all instances of ‘primary immunodeficiency diseases’ to ‘inborn errors of immunity’.
* Change to the conditions for additional dose clarifying that clinician should list the patient’s current IgG level in the comment box.
* Corrected a transcription error in the initial review criteria for indication 1.
* Corrected a transcription error in the transitioning authorisation review criteria for indication 1.
* Corrected other minor typographical errors.
 | December 2024 | 3.5 |
| * Reduce the age to 2 years (from 4 years) for indication 1 (replacement therapy in common variable immune deficiency).
 | November 2023 | 3.4 |
| * 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 |
| * 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 – 0.6 g/kg every four weeks or more frequently.
* Separate doses are now available for intravenous and subcutaneous immunoglobulin administration.
 | October 2019 | 3.2 |
| 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 |
| Pyoderma gangrenosum (PG) | * Severe PG when immunosuppressant and biologic therapy is either ineffective or inappropriate due to unacceptable side effects
* 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 haemopoietic 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.
 | * Added links to exclusion criteria.
* Updated links for several references.
 | April 2025 | 3.6 |
| * Corrected the spelling of ‘haemopoietic’ in the medical condition name and exclusion criteria.
* Change to conditions for additional dose clarifying that the clinician should list the patient’s current IgG level in the comment box.
 | December 2024 | 3.5 |
| * 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 |
| * 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
 | * Clarified the maximum dose per period per kilogram.
 | December 2024 | 3.3 |
| * 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 |
| Toxic epidermal necrolysis (TEN; Lyell syndrome)/Stevens-Johnson syndrome (SJS) | * Toxic epidermal necrolysis (TEN)or Stevens–Johnson syndrome / toxic epidermal necrolysis overlap (SJS/TEN) with rapid evolution and >10% body surface area affected
 | * Added clarity to the dosage text.
 | December 2024 | 3.1 |
| Toxic shock syndrome (TSS) | * Early use in streptococcal TSS
* Staphylococcal TSS where rapid improvement is not obtained with fluid resuscitation, inotropes, surgery, antibiotic therapy and other supportive measures
 | * Remove the qualifying criterion regarding supportive measures from indication 1.
* Update several links in the bibliography.
 | April 2025 | 3.1 |
| Vaccine associated myocarditis and pericarditis (VAMP) | * Treatment of vaccine associated myocarditis and pericarditis (VAMP)
 | * Updated the qualifying criteria to clarify that vaccine should be given within the past 20 days to match the assessment instructions.
 | December 2024 | 3.1 |