

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

# Transplant Medicine Conditions - Summary of Criteria Changes

The *Criteria for clinical use of immunoglobulin in Australia* (Criteria) is under a continuous review cycle to enable appropriate access. The table below summarises subsequent changes made by medical condition and indication to the Criteria following the publication of Version 3 of the criteria since October 2018. 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** |
| --- | --- | --- | --- | --- |
| Solid organ transplantation | 1. Immediate pre and/or post-transplant where donor specific antibody(s) prevent transplantation or threaten transplantation 2. Initial treatment of acute antibody mediated transplant rejection 3. Treatment of ongoing active antibody mediated transplant rejection 4. Ongoing desensitisation of patients to improve the likelihood of transplantation 5. Treatment or prevention of graft rejection where the use of conventional immunosuppressive therapies is contraindicated or poses a threat to the graft or patient | Indication 3   * The criterion in Initial and continuing review criteria has been updated to make the biopsy evidence item non mandatory. | March 2023 | 3.1 |
| All indications   * The dosing controls have been updated to allow dose frequency of between 1 to 28 days to account for variable dosing. |
| Indication 5   * The earliest valid date of transplant has been extended to capture solid organ transplant more than 6 years in the past. |
| Indications 2 and 3   * The qualifying criteria have been updated to allow for inclusion of evidence for transplants other than kidney or heart transplants. |
| Indication 5   * The qualifying and review criteria have been updated to clarify that patients who have no history of immunoglobulin treatment can qualify against the Criteria. |
| Indication 4, indications 1, 2, 4   * Correction of typographical errors. |
| Indications 1 and 2   * The dose wording has been updated to clarify that the doses can be administered as divided doses. |
| Indication 3   * The dose name has been updated to be consistent with other dose names in BloodSTAR. |
| Indication 2   * Correction of data entry error to allow divided dose in BloodSTAR. |
| Indication 3   * The dose text has been updated to reflect that IVIg may be given with or without plasma exchange. |
| Indication 3   * The dose text and Max Dose have been increased from 0.5 to 1.0g/kg. |