# Specialist Working Group for Haematology

**Proposed changes to the *Criteria for the clinical use of intravenous immunoglobulin in Australia, Second Edition***

| ITEM | CRITERIA FOR THE CLINICAL USE OF INTRAVENOUS IMMUNOGLOBULIN IN AUSTRALIA, SECOND EDITION (CRITERIA) | PROPOSED REVISIONS TO THE CRITERIA | SWG RATIONALE FOR PROPOSED CHANGE<br>(A) Administrative)<br>(B) Progressive<br>(C) Programmed |
|---|---|---|---|
| **Condition Name** | **Post-transfusion purpura (PTP)** | **Post-transfusion purpura (PTP)** | |
| **Specialty** | Haematology | Haematology | |
| **Chapter** | 6 | 6 | |
| **Specific Conditions** | | | |
| **Level of Evidence** | Small case studies only; insufficient data (Category 4a). | Small case studies only; insufficient data (Category 4a). | |
| **Justification for Evidence Category** | Mueller-Eckhardt and Kiefel (1988) evaluated the effect of high-dose IgG (HDIgG) in 11 PTP cases investigated in one institution and summarised clinical data on 8 additional reported cases. Of 17 cases, 16 had good or excellent response to HDIgG, attaining normal platelet counts within a few days; only one failure was observed. Five patients relapsed, but attained complete remission after a second course (dose) of IgG. Total IgG doses per course were in the range 52–180 g. Five different IgG preparations were used and seemed similarly effective. No adverse reactions were observed. The authors conclude that HDIgG is the treatment of choice for PTP. | Mueller-Eckhardt and Kiefel (1988) evaluated the effect of high-dose immunoglobulin G (HDIgG) in 11 PTP cases investigated in one institution, and summarised clinical data on 8 additional reported cases. Of 17 cases, 16 had good or excellent response to HDIgG, attaining normal platelet counts within a few days; only one failure was observed. Five patients relapsed, but attained complete remission after a second course (dose) of IgG. Total IgG doses per course were in the range of 52–180 g. Five different IgG preparations were used and seemed similarly effective. No adverse reactions were observed. The authors conclude that HDIgG is the treatment of choice for PTP. | |

| ITEM | CRITERIA FOR THE CLINICAL USE OF INTRAVENOUS IMMUNOGLOBULIN IN AUSTRALIA, SECOND EDITION (CRITERIA) | PROPOSED REVISIONS TO THE CRITERIA | | | SWG RATIONALE FOR PROPOSED CHANGE<br>(A) Administrative)<br>(B) Progressive<br>(C) Programmed |
|---|---|---|---|---|---|
| **Description and Diagnostic Criteria** | PTP is caused by antibodies to platelet-specific antigens, usually anti-HPA1a. PTP may result in profound thrombocytopenia with associated life-threatening bleeding. While the platelet count typically recovers spontaneously, this can take several weeks or more.<br><br>Specialised investigations (antibody screening, patient/donor genotyping) and antigen-matched platelet and/or red cell transfusion support may be required — contact the Blood Service for more information. | PTP is caused by antibodies to platelet-specific antigens, usually anti-HPA1a. PTP may result in profound thrombocytopenia with associated life-threatening bleeding. While the platelet count typically recovers spontaneously, this can take several weeks or more.<br><br>Specialised investigations (antibody screening, patient/donor genotyping) and antigen-matched platelet and/or red cell transfusion support may be required. Contact the Blood Service for more information. | | | |
| **Diagnosis is required** | | Yes | Which Speciality | Haematologist or General physician | SWG recommends that diagnosis by specialists as listed is required. This meets the current criteria recommendation for laboratory confirmation. (A) |
| **Diagnosis must be verified** | | No | Which Specialty | | |
| **Exclusion Criteria** | | | | | |
| **Indication for use** | Treatment of profound thrombocytopenia associated with bleeding. | **PTP or suspected PTP with thrombocytopenia associated with a risk of life-threatening bleeding.** | | | Slight rewording of indication to require the diagnosis of PTP for this condition and a risk of life threatening bleeding. (A) |
| **Qualifying Criteria** | Clinical diagnosis/suspicion of PTP with thrombocytopenia associated with life- | • Clinical diagnosis or suspicion of PTP with profound thrombocytopenia <30 x $10^9$/L. | | | SWG revised the qualifying criteria to include the risk of life threatening bleeding rather than waiting for a life threatening bleed to occur. (A) |

| ITEM | CRITERIA FOR THE CLINICAL USE OF INTRAVENOUS IMMUNOGLOBULIN IN AUSTRALIA, SECOND EDITION (CRITERIA) | PROPOSED REVISIONS TO THE CRITERIA | SWG RATIONALE FOR PROPOSED CHANGE<br>(A) Administrative)<br>(B) Progressive<br>(C) Programmed |
|---|---|---|---|
| | threatening bleeding.<br><br>**Note:** Laboratory confirmation is desirable where possible in the time frame (usually an urgent, life-threatening clinical situation). | AND<br><br>• A risk of life-threatening bleeding. | |
| **Review Criteria** | • Platelet counts in the days and weeks following IVIg.<br><br>• Resolution of bleeding. | Review is not mandfated for this indication however the following criteria may be useful in assessing the effectiveness of therapy.<br><br>**Outcome data to be measured**<br><br>• maximum platelet count within 72 hours of Ig treatment of greater than 30 x $10^9$/L and double the pre-teratment count<br><br>• prevention of or reduction in bleeding risk. | Outcome data have been defined. (A)<br><br>In view of the lack of data for this condition, and multiple single dosing, discussion regarding considering an option to insert a question when prescribers returned for multiple single doses - to confirm whether a response was gained following the last dose. It was agreed that in the event of or risk of a life threatening bleed, further therapy would not be withheld whether the patient had responded or not. It was noted that it is a rare condition and any data likely to be available would not materially add to the evidence base. It was acknowledged as being very hard to collect any data – that will improve the current lack of evidence. |
| **Dose** | 1 g/kg as a total dose, repeated if necessary<br><br>**Refer to the current product information sheet for further information.**<br><br>**The aim should be to use the lowest dose possible that achieves the appropriate clinical** | **Induction Dose** - 1 g/kg as a total dose, repeated if necessary.<br><br>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.<br><br>**Refer to the current product information sheet** | Dosing unchanged. |

| ITEM | CRITERIA FOR THE CLINICAL USE OF INTRAVENOUS IMMUNOGLOBULIN IN AUSTRALIA, SECOND EDITION (CRITERIA) | PROPOSED REVISIONS TO THE CRITERIA | SWG RATIONALE FOR PROPOSED CHANGE<br>(A) Administrative)<br>(B) Progressive<br>(C) Programmed |
|---|---|---|---|
| | **outcome for each patient.** | **for further information.** | |

**BIBLIOGRAPHY**


Gonzalez, CE & Pengetze, YM 2005, 'Post-transfusion purpura', *Current Haematology Reports*, vol. 4, no. 2, pp. 154–9.

Mueller-Eckhardt, C & Kiefel, V 1988, 'High-dose IgG for post-transfusion purpura – revisited', *Blut*, vol. 57, no. 4, pp. 163–7.


**END OF DOCUMENT**