Version 2

Please don't Ignore this.

The Ig Criteria are changing.

Version 3

FACTSHEET FOR HEALTH PROFESSIONALS:

Pure red cell aplasia (PRCA)

Indication for Ig use:

- **Pure red cell aplasia (PRCA) associated with Parvo B19 infection in immunocompromised patients or autoimmune mediated refractory to immunosuppressant medication**

WHY ARE THE *CRITERIA* CHANGING?

The *Criteria for Immunoglobulin Use in Australia* (the *Criteria*) is changing to Version 3. These changes will apply in BloodSTAR from 22 October 2018.

Immunoglobulin (Ig) is a precious biological product, and as such, its use should be consistent with the evidence base and prescribed for the treatment of patients who are likely to benefit from immunoglobulin therapy, and for whom there are no safe and effective alternative treatments.

The continual significant annual growth in Ig use, the high cost of Ig products and the potential for supply shortages have maintained the focus of Australian governments on ensuring use remains consistent with an evidence-based approach and that Ig is able to be accessed under the National Blood Arrangements for those patients with the greatest clinical need.

The *Criteria* describes the conditions and indications for which the use of Ig is appropriate and funded under the National Blood Agreement. The *Criteria* was developed and has been subsequently reviewed by expert specialist working groups using the best available medical evidence.

HOW DOES IT AFFECT ME?

- The *Criteria* requires that the treating medical specialist in BloodSTAR must be a particular type of specialist. These specialist types are confirmed in accordance with registration in the Australian Health Practitioners Regulation Agency (AHPRA).
- The qualifying criteria will be more definitive in some conditions and additional evidence will be required. It may take a little more time to complete the additional information required.
- While higher doses may be initially required to gain control of active disease in some conditions, the minimal effective dose should be used for ongoing treatment.
- Formal review will always be needed to continue receiving funded Ig.
- Medical officers are asked to enter outcomes into the review criteria for all conditions, not just those that require continuing therapy. This will support future development of the *Criteria*.
- There will be better guidance for patient eligibility and requirements to trial off Ig therapy.

REVISION SUMMARY FOR PURE RED CELL APLASIA (PRCA)

- Existing patients will remain on current arrangements until authorisation expiry. If further treatment with Ig is required, a new initial authorisation request can be made.
- The diagnosing specialist is limited to haematologists.
- Confirmation of the bone marrow biopsy findings is required.
- For autoimmune mediated aplasia, Ig is reserved for patients who have demonstrated an inadequate response to immunosuppressant therapies, unless there is a contraindication or intolerable side effects to such therapies.
- The dose is described as up to 2g/kg. Up to two subsequent doses are available at monthly intervals should bone marrow recovery be incomplete.
- For detailed condition information please refer to the condition pdf available at www.blood.gov.au/ig-criteria-version-3.