Version 2

Please don't Ignore this.

The Ig Criteria are changing.

Version 3

FACTSHEET FOR HEALTH PROFESSIONALS:

Anti-neutrophil cytoplasmic antibody (ANCA) [Proteinase 3 (PR3) or myeloperoxidase (MPO)]-positive systemic necrotising vasculitis

Indication for Ig use:

- **Anti-neutrophil cytoplasmic antibody (ANCA) positive systemic necrotising vasculitis failing to respond to corticosteroids and cytotoxic immunosuppression**
- **Relapse in Anti-neutrophil cytoplasmic antibody (ANCA) positive systemic necrotising vasculitis resistant following response to Ig therapy**

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 ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODY (ANCA) [PROTEINASE 3 (PR3) OR MYELOPEROXIDASE (MPO)]- POSITIVE SYSTEMIC NECROTISING VASCULITIS

- Existing patients will remain on current arrangements until authorisation expiry. If required, further treatment may be accessed via a new application.
- The diagnosing and reviewing specialists have been limited to rheumatologists, immunologists and nephrologists.
- Ig therapy is reserved for patients who have failed to respond to more effective alternative therapies, including Rituximab, or where these are contraindicated.
- Evidence of persistent active disease is required as assessed by at least two markers including ANCA level, BVAS, ESR and C-reactive protein.
- Initial Ig treatment is limited to a period of six months, at which point a trial off Ig therapy is required in order to establish whether remission has been achieved as well as to ensure that ongoing treatment for the longer term is limited to responding patients. Patients who relapse after the trial off will be eligible for further Ig therapy, where evidence of initial response to Ig can be demonstrated.
- Once the disease is stable, a further trial off Ig therapy will be considered to see if the patient may be in remission.
- An Induction dose of 2 g/kg is described, and the maximum dose for maintenance treatment is set at 1 g/kg. For patients being treated above this dose a process to gradually reduce dose should be implemented.
- For detailed condition information please refer to the condition pdf available at www.blood.gov.au/ig-criteria-version-3.