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 AUTOIMMUNE RETINOPATHY (FORMERLY AUTOIMMUNE UVEITIS)

- Existing patients will transition automatically to the new criteria. For these patients, additional clinical information will be required, as a one-off during transition, to ensure the patient meets the new criteria.
- While any Ig specialist can request Ig for AIR, if the diagnosing specialist is not an ophthalmologist, the diagnosis must be verified by ophthalmologist.
- Confirmation by electoretinography of persistent severe disease threatening eyesight, which is limited to the retinal plane, is required. Integrity of macular anatomy should be confirmed by optical coherence tomography testing. Uveitis with features of anterior or posterior chamber inflammation is excluded.
- Ig therapy is reserved for patients who have failed to respond to immunosuppressant therapy and steroids unless these agents are contraindicated.
- Review is required after the first three months and annually thereafter. Improvement at review must be determined by an ophthalmologist. If the reviewing specialist is not an ophthalmologist, a letter from an ophthalmologist is required.
- An Induction dose of 1.5 g/kg, and maintenance dosing of 0.4–1.5 g/kg is described.