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.

FACTSHEET FOR HEALTH PROFESSIONALS:
Sjögren’s syndrome associated neuropathy
(formerly Sjögren’s syndrome)

Indication for Ig use:

- Severe, primary Sjögren's syndrome associated neuropathy that is unresponsive to corticosteroid and immunosuppressant therapy
- Relapse of Sjögren's syndrome associated neuropathy within six months of trial off Ig therapy
Please don’t ignore this.
The Ig Criteria are changing.

REVISION SUMMARY FOR SJÖGREN’S SYNDROME ASSOCIATED NEUROPATHY (FORMERLY SJÖGREN’S SYNDROME)

- Existing patients will remain on the current arrangements until the next due review. At that time prescribers will need to select the appropriate specific condition from a dropdown list. For these patients, additional clinical information will be required, as a one-off during transition, to ensure the patient meets the new criteria.

- Diagnosis and the initial review are limited to neurologists. Subsequent reviews can be managed by a neurologist, immunologist or rheumatologist.

- Demonstration of significant disability in patients with primary Sjögren’s syndrome associated neuropathy without necrotising vasculitis is required.

- Objective measure of disability and response to treatment is required. The use of the adapted Modified Rankin Scale (MRS) in all patients provides a consistent baseline that can be compared for clinical response to Ig therapy at review.

- Ig therapy is reserved for patients who have failed to respond to corticosteroids and immunosuppressant agents, unless there is a contraindication or intolerable side effects to such therapies.

- Demonstration of clinical benefit in relation to symptoms and disability post infusion is required after an initial treatment period of four months, and six monthly thereafter, in order to access further treatment.

- Cessation of Ig therapy should be considered for all patients after 12 months of treatment unless contraindicated.

- For patients who relapsed within six months of a trial off Ig therapy, further therapy may be requested using a separate indication, and a further trial off should be considered each 12 months.

- Dosing is set as 1-2 g/kg for induction and for maintenance therapy as 0.4-1 g/kg four to six weekly. A maximum total dose of 1g/kg may be given in any four week period.