Version 2

Please don't Ignore this.

The Ig Criteria are changing.

Version 3

FACTSHEET FOR HEALTH PROFESSIONALS:

Childhood epileptic encephalopathy (formerly Epilepsy)

Indication for Ig use:

- **Children with epileptic encephalopathy resistant to anti-epileptic medications and steroid therapy or steroid responsive but dependant**
- **Relapse of epileptic encephalopathy following a trial of weaning from Ig therapy in a patient previously demonstrating response**

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 CHILDHOOD EPILEPTIC ENCEPHALOPATHY (FORMERLY EPILEPSY)

- 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 and indication 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 review is limited to neurologists.
- Diagnosis by EEG is required, and patients must demonstrate refractory epilepsy (at least weekly) with neurodevelopmental or cognitive issues. The keeping of a seizure diary is encouraged in order to be able to assess the clinical response to Ig therapy.
- Ig therapy is reserved for patients who have failed to respond to corticosteroids and more than two anticonvulsants or surgery, unless there is a contraindication or intolerable side effects to such therapies.
- Demonstration of clinical benefit in relation to symptoms and severity and/or frequency of seizures are required after an initial treatment period of three months, and annually thereafter in order to access further treatment.
- Cessation of Ig therapy should be considered for all patients after 12 months of treatment unless contraindicated. If patients relapse and seizures start again after Ig therapy has been stopped, a further request for ongoing Ig therapy can be made for those who have previously responded.
- Dosing is set as 2 g/kg for induction and for maintenance therapy as 1 g/kg over two to five days monthly.
- For detailed condition information please refer to the condition pdf available at www.blood.gov.au/ig-criteria-version-3.