Version 2

Please don't Ignore this.

The Ig Criteria are changing.

Version 3

FACTSHEET FOR HEALTH PROFESSIONALS:

Inflammatory myopathies:polymyositis (PM), dermatomyositis (DM) and necrotising autoimmune myopathy (NAM)

(formerly Inflammatory myopathies: polymyositis [PM], dermatomyositis [DM] and inclusion body myositis [IBM])

Indication for Ig use:

- Treatment of significant muscle weakness or dysphagia unresponsive to corticosteroids and other immunosuppressant agents in adults with biopsy-proven PM or DM or NAM or children with clinical, biochemical and imaging abnormalities consistent with definite PM or DM or NAM

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.

Please don't Ignore this.

The Ig Criteria are changing.

REVISION SUMMARY FOR INFLAMMATORY MYOPATHIES:POLYMYOSITIS (PM), DERMATOMYOSITIS (DM) AND NECROTISING AUTOIMMUNE MYOPATHY (NAM) (FORMERLY INFLAMMATORY MYOPATHIES: POLYMYOSITIS [PM], DERMATOMYOSITIS [DM] AND INCLUSION BODY MYOSITIS [IBM])

- 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 review is limited to immunologists, neurologists and rheumatologists.
- Diagnosis proven by muscle biopsy in adult patients, and either muscle biopsy or typical MRI and muscle enzyme changes with rash in children, is required.
- Objective measure of muscle weakness and response to treatment is required. The use of the Medical Research Council (MRC) sum score in an adult, or the Childhood Myositis Assessment Scale (CMAS) in a child, provides a consistent baseline that can be compared for clinical response to Ig therapy at review.
- For patients with significant dysphagia limiting dietary intake, a description of the degree of disability is required. Where possible video-fluoroscopy should be used to demonstrate pharyngeal involvement, unless video-fluoroscopy presents an unacceptable risk.
- Ig therapy is reserved for patients who have failed to respond to corticosteroid treatment, unless such treatment is contraindicated or has resulted in unacceptable side effects.
- Demonstration of clinical benefit in relation to muscle weakness or dysphagia is required after an initial treatment period of four 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.
- Dosing is set as 2 g/kg for induction and for maintenance therapy as 1 g/kg four weekly. Existing patients may require transitioning to the dose levels permitted under this condition, if these are being exceeded.
- For detailed condition information please refer to the condition pdf available at www.blood.gov.au/ig-criteria-version-3.