Version 2

Please don't Ignore this.

The Ig Criteria are changing.

Version 3

FACTSHEET FOR HEALTH PROFESSIONALS:

Epidermolysis bullosa acquista (EBA)

Indication for Ig use:

- **Persistent severe EBA refractory to conventional immunosuppressive therapy**
- **Treatment of an ongoing flare of EBA disease in responding patients who have ceased 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 EPIDERMOLYSIS BULLOSA ACQUISTA (EBA)

- Existing patients will remain on current arrangements until authorisation expiry. Thereafter a new request will need to be submitted to access further therapy.
- The diagnosing and treating specialist type will be limited to dermatologists and immunologists.
- Confirmation of persistent and severe disease confirmed by biopsy or positive immunofluorescence test is required.
- Ig is reserved for patients who have demonstrated an inadequate response to a standard course of corticosteroids and immunosuppressant agents, unless there is a contraindication or intolerable side effects to such therapies.
- For patients with ongoing flares of disease, who are known to respond to Ig therapy, clinical benefit must be demonstrated after the first four months, and six monthly thereafter to access continuing therapy. Immunosuppressant medication is required to be given concurrently.
- Once patients are stable they should have a trial off Ig therapy.
- The dosing has been revised to describe an initial dose of 1.5 – 2g/kg, monthly for three months. If further treatment is required maintenance therapy can be prescribed as 0.4 g/kg four to six-weekly.
- For detailed condition information please refer to the condition pdf available at www.blood.gov.au/ig-criteria-version-3.