

Please don't Ignore this.

The **Ig** Criteria are changing.

FACTSHEET FOR HEALTH PROFESSIONALS: Bullous pemphigoid (BP)

Indication for Ig use:

Bullous pemphigoid (BP) resistant to corticosteroids and immunosuppressant therapy or when these agents are contraindicated

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.

CHANGES TO BULLOUS PEMPHIGOID (BP)

- 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.
- Dermatologists continue to be the main diagnosing and reviewing specialists. Immunologists are also now included.
- Confirmation that diagnosis has been proven by biopsy or demonstration of autoantibody serology is required. An indication of the sites involved and degree of severity will need to be advised.
- 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.
- A review of the number of lesions is used to assess clinical benefit every six months to access ongoing therapy.
- Disease is generally self-limiting so trial off or dose reduction is appropriate and best practice.
- A maximum dose of 2g/kg has been set. Patients on a higher dose may need to reduce dosing. A lower dose has been created to support weaning off.
- For detailed condition information please refer to the condition pdf available at www.blood.gov.au/ig-criteria-version-3