

Please don't Ignore this.

The **Ig** Criteria are changing.

FACTSHEET FOR HEALTH PROFESSIONALS: Systemic capillary leak syndrome (SCLS)

Indication for Ig use:

- Prevention of recurrent life-threatening episodes of hypotensive shock with hypoalbuminaemia in diagnosed Systemic capillary leak syndrome (SCLS)

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 SYSTEMIC CAPILLARY LEAK SYNDROME (SCLS)

- 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.
- The types of diagnosing and treating specialists have been limited to general physicians, emergency medicine specialists, intensivists and immunologists.
- Formal qualifying criteria have been developed to allow six months initial treatment for patients with recurrent episodes of unexplained hypotension and oedema and when hospitalisation has been required on more than one occasion in the previous six months.
- Review is required by a general physician or immunologist, and clinical benefit must be demonstrated after the first six months of treatment and annually thereafter, to access further treatment.
- Once disease activity is stable or in remission, a trial off Ig therapy should be commenced or a reduction in dose considered. If patients do relapse once Ig treatment has been stopped, a further request to restart ongoing Ig therapy can be made.
- Induction dosing of 1-2g/kg, and maintenance dosing of 0.4-2g/kg monthly has been defined. If existing patients are being treated in excess of the new dosing range, a plan to reduce dose will be required.
- For detailed condition information please refer to the condition pdf available at www.blood.gov.au/ig-criteria-version-3.