

Please don't Ignore this.

The **Ig** Criteria are changing.

FACTSHEET FOR HEALTH PROFESSIONALS:

Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infections (PANDAS) or paediatric acute neuropsychiatric disorders (PANS) (formerly Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infection [PANDAS])

Indication for Ig use:

- Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infections (PANDAS) or paediatric acute neuropsychiatric disorders (PANS) unresponsive to trial of antibiotic therapy, and significant impairment requiring intervention
- Relapse of paediatric acute neuropsychiatric disorders (PANDAS) or paediatric acute neuropsychiatric disorders (PANS) symptoms within three months of commencement of trial off 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.

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REVISION SUMMARY FOR PAEDIATRIC AUTOIMMUNE NEUROPSYCHIATRIC DISORDER ASSOCIATED WITH STREPTOCOCCAL INFECTIONS (PANDAS) OR PAEDIATRIC ACUTE NEUROPSYCHIATRIC DISORDERS (PANS) (FORMERLY PAEDIATRIC AUTOIMMUNE NEUROPSYCHIATRIC DISORDER ASSOCIATED WITH STREPTOCOCCAL INFECTION [PANDAS])

- 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.
- Diagnosis and the initial review are limited to neurologists and immunologists.
- Confirmation of a sudden onset of obsessive-compulsive disorder or severely restricted food intake associated with infection is required, along with a description of additional neuropsychiatric symptoms.
- Ig therapy is reserved for patients who have failed to respond to standard antibiotic therapy.

- Objective measure of disability and response to treatment is required. The use of the Modified Rankin Scale (MRS) is required at qualifying, and one of the Tics-Yale, OCD-CY-BOCS or Anxiety-SPENCE scales is required to assess improvement at review.
- Demonstration of clinical benefit in relation to symptoms and disability is required after an initial treatment period of one month, and every three months thereafter, to access further treatment.
- In stable patients, a trial of weaning towards cessation should be considered at each review.
- Dosing is set as up to 2 g/kg for induction and for maintenance therapy as 1–1.5 g/kg four to six 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.