Version 2

Please don't Ignore this.

The Ig Criteria are changing.

Version 3

FACTSHEET FOR HEALTH PROFESSIONALS:

Version 3 Criteria coming soon!

WHEN IS THE *CRITERIA* CHANGING?

The *Criteria for Immunoglobulin Use in Australia* (the *Criteria*) is changing to Version 3 from 22 October 2018.

The *Criteria* will be released electronically within BloodSTAR and will also be available at www.criteria.blood.gov.au. A printed version will no longer be available.

Information for each medical condition can be printed from BloodSTAR or www.criteria.blood.gov.au if required, but any printed version must regularly be checked for currency.

WHY IS THE *CRITERIA* CHANGING?

To align with new evidence

To ensure those whose health is most likely to be improved with Ig therapy can get it

To manage the growth in demand for this precious, human-derived product.

Immunoglobulin (Ig) is a precious biological product derived from donated blood plasma, 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 relatively high cost of Ig products and the potential for supply shortages mean that it is important to maintain a focus on ensuring that 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 demand for Ig in Australia continues to grow at a consistent annual rate of more than 10%. In 2016-17, a total of 5.54 million grams of Ig was issued, representing a cost of $532.3 million nationally (including the cost of plasma collections).
- The rate of increase of Ig demand is significantly above the rate of increase of Australian plasma collections by the Australian Red Cross Blood Service, with the result that the proportion of Ig demand that is met by imported Ig products is also increasing each year.

The *Criteria* describes the conditions and indications for which the use of Ig is appropriate and government funded under the National Blood Agreement. Requests to access publicly funded immunoglobulin products in Australia must be authorised under the *Criteria*.

- The *Criteria* was developed in 2008 based on the available evidence and the advice of clinical specialists who are the experts in their field, and was partially reviewed and updated in 2012.

The *Criteria* has again been extensively reviewed by four expert Specialist Working Groups (in Neurology, Immunology, Haematology and Transplant Medicine) under the auspices of the National Immunoglobulin Governance Advisory Committee (NIGAC) and the National Blood Authority. All changes to the *Criteria* have also been subject to public consultation. Through this process the *Criteria* have been significantly strengthened in a number of important respects, as outlined further below.

- The *Criteria* has been revised to ensure that patients whose health is most likely to be improved with Ig therapy can access funded Ig products for clinically appropriate purposes, where there are no safe, effective and cost-effective alternative treatments

NATIONAL BLOOD AUTHORITY AUSTRALIA

Ig Governance

BLOODSTAR

www.blood.gov.au

Visit www.blood.gov.au/Ig-governance for more information about Ig Governance and the *Criteria*.
Phone: 13000 BLOOD (25663) Email: support@blood.gov.au

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- The revised *Criteria* will more clearly articulate and standardise the qualifying criteria, dosing controls and length of authorisations and define clinical outcomes for continuing therapy to be able to access publicly funded Ig.
- The revised *Criteria* will assist with consistency of access and ensuring that the growth in demand for this precious, human-derived product is based on justifiable factors.
- The revisions will bring the *Criteria* are in line with current evidence and established clinical best practice.

The changes to the *Criteria* will also assist hospitals in meeting Standard 7 – Blood Management Standard of the National Safety and Quality Service Standards (Second Edition).

WHAT IS CHANGING AND HOW DOES IT AFFECT ME?

Moving authorisations to the new version

Transition of existing authorisation records to the new version will largely be managed automatically in BloodSTAR from the commencement of the new version of the *Criteria* on 22 October 2018, but some actions may be required of prescribers in order to complete this process, as outlined below. Further specific information about this process will be communicated to prescribers in the near future.

- Most current patient authorisations will transition automatically when the new *Criteria* are released
- The initial qualifying criteria for some conditions is changing, so some patients will need to requalify in order to transition
- For some patients BloodSTAR may require some additional information at a patient's first review after transitioning to the new version
- Further information required by BloodSTAR may include selection of the appropriate revised indication or specific condition, or providing clinical evidence such as pathology results, or confirming a patient's clinical response to Ig
- For NSW health providers –existing patient authorisations will be entered into BloodSTAR by a legacy process before the new version is released. After this, current authorisations will move to the new *Criteria* in the same manner as outlined above

Changes to specialist requirements

In some conditions the revised *Criteria* will require patients to be diagnosed or reviewed by a particular type of specialist (for example an Immunologist) to access funded Ig.

- Patients may need to be referred to a different specialist as it is important to ensure correct diagnosis and management. Rural patients may benefit from telehealth or remote reviews
- Some patients may need to see their specialist more frequently to ensure they are responding to Ig therapy
- In some conditions the revised *Criteria* allow for the diagnosis to be made by additional specialist medical officers who may already manage patients with these conditions, which will improve ease of access

BloodSTAR checks the registration and specialty of all medical officers with the Australian Health Practitioner Regulation Agency (AHPRA). To be recognised as a specialist in BloodSTAR a clinician must be registered for the relevant specialist qualifications with AHPRA.

- BloodSTAR will only recognise a clinician's specialties as registered in AHPRA
- BloodSTAR will now provide an early warning message during the process of seeking authorisation if a clinician's speciality does not accord with the *Criteria* requirements, to allow correction before submitting the authorisation request

BloodSTAR improvements

BloodSTAR functionality has been improved so the system is easier to use and navigate. Information on the changes will be provided to all BloodSTAR users.

- Improvements in the keyword search function will make it easier to find conditions when commencing an authorisation request
- Data entry and requests have been improved in response to user feedback

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Medical Conditions in the *Criteria*

There will be changes to a small number of medical conditions

- A small number of conditions in the *Criteria* have been merged with other conditions to better align with the predominant clinical features
- Following a review of the evidence, and based on expert clinical opinion and public consultation, Ig will no longer be funded for a small number of conditions. This is because there has been limited use, alternative therapies have been demonstrated to be more effective, or there is insufficient evidence to support the use of Ig therapy for those conditions

Indications for Ig Use

Indications for Ig therapy are now more descriptive to better support the decision to provide access to funded Ig therapy and assist the prescriber to select the appropriate criteria and dosing regimens.

Qualifying *Criteria*

The *Criteria* have been reviewed by expert specialist groups and updated to reflect current evidence and best clinical practice.

- For some conditions more evidence will be required to confirm that a patient has trialled first line therapies, where they are available and particularly if they are more cost effective
- In some cases BloodSTAR may ask for more clinical information (such as pathology results) to confirm the diagnosis and requirement for Ig therapy
- In some conditions, the *Criteria* are more definitive on when Ig therapy is indicated and more direction is provided regarding the types of investigations to be used in the assessment of patients. These assessment methods will provide consistency and allow comparison of results to determine clinical response to Ig therapy for re-authorisation at review. It may take a little more time to complete the additional information required.

Review *Criteria*

Formal patient review is required to continue receiving funded Ig as ongoing therapy. Minimum levels have been defined for the expected clinical response to Ig therapy in most conditions.

- The revised *Criteria* will provide greater guidance for prescribers regarding patient eligibility, and when a patient may be ready to trial off Ig therapy. For many conditions, patients who have previously trialled off Ig therapy and then relapsed will be covered by a specific indication
- Reporting of review outcomes will be possible and encouraged for all conditions, including those without ongoing treatment. For conditions that do not have ongoing treatment minimal data entry will be required for this reporting

Dosing

Dosing has now been defined for many conditions and recommended dosing levels are clearly described in the revised *Criteria*

WHERE CAN I FIND MORE INFORMATION?

More information will be added to the *Criteria* 3 information page www.blood.gov.au/igcriteria-version3 as it becomes available.

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