Version 2

Please don't Ignore this.

The Ig Criteria are changing.

Version 3

SUMMARY 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.

Governments' fund the supply of Ig so that it can be provided free of charge to patients who have a condition that meets the qualifying criteria for supply as outlined in the *Criteria*. Requests to access publicly funded immunoglobulin products in Australia must be authorised under the *Criteria*.

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). Of this amount, a significant proportion of Ig is imported from overseas suppliers.

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 *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.

Strengthening the *Criteria* will help to ensure ethical expenditure of government funds in accordance with Standard 7 – Blood and Blood Products of the National Safety and Quality Service.

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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HOW WILL THE CHANGES AFFECT PRESCRIBERS?

The new *Criteria* will be released in an online format only in BloodSTAR in October 2018

Some current authorisations will move to the new *Criteria* automatically, while others may require prescribers to provide more information at the next patient review

Indications will be more descriptive to help prescribers select the appropriate one for each patient

The qualifying criteria will be more definitive in some conditions and additional evidence may be required

In a small number of situations funding of Ig therapy has been withdrawn

There will be better guidance for patient eligibility and requirements for patients to trial off Ig therapy

A formal review of patient outcomes will need to be reported periodically in order to continue authorisation to receive funded Ig, for all ongoing conditions

Reporting of review outcomes will be available for all conditions, not just those with an option to continue treatment

Dosing controls have been reviewed and are more definitive where appropriate

Note: For NSW health providers –existing patient authorisations will be entered into BloodSTAR by a legacy process before the new version is released. Once this happens authorisations will move to the new *Criteria* as explained above.

HOW WILL THE CHANGES AFFECT PATIENTS?

In some conditions patients may need to be diagnosed or reviewed by particular types of specialists, which may be different from current arrangements. Some patients may benefit from telehealth or remote reviews

There are some changes to qualifying criteria for certain conditions

More clinical information may be needed to support the initial or ongoing authorisation to receive funded Ig

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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