Ig Governance Criteria and Progress Updates - 2018

October 2018

Version 3 of the Criteria

The *Criteria for Immunoglobulin Use in Australia* (the Criteria) changed to Version 3 on 22 October 2018.

The Criteria has been released electronically within BloodSTAR and is also available at www.criteria.blood.gov.au.A printed version is no longer 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 did the Criteria Change?

- 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
- 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 has changed and how does it affect me?

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

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.

Moving authorisations to the new version

Transition of existing authorisation records to the new version is largely 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 is available in the condition specific factsheets and summaries of medical condition changes below.

- Most current patient authorisations have transitioned automatically when the new Criteria was released
- The initial qualifying criteria for some conditions has changed, 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 were entered into BloodSTAR by a legacy process before the new version was released. These authorisations will also transition to the new Criteria in the same manner as outlined above.

Fact Sheets for printing

The following fact sheets are available for printing and circulation:

Detailed information from this webpage for Health Professionals

Summary fact sheet for Health Professionals

Summary fact sheet for Patients

Summaries of medical condition changes in the Criteria by specialty for Health Professionals

Condition specific fact sheets

July 2018

Important changes coming 22 October 2018

Version 3 of the Criteria is coming!

The Ig Governance Program is pleased to announce that Version 3 of the Criteria is planned for release on **22 October 2018**. The team is continuing to focus efforts on entering the new Criteria into BloodSTAR, ready for implementation.

What are the key things you need to know now?

- The new Criteria will be released in an online format only in BloodSTAR
- Some authorisations will be moved automatically, more information may be requested for others at the next review
- Indications will be more descriptive to help you select the appropriate one for your patient
- The qualifying criteria will be more definitive for some conditions and additional evidence will be required, so it may take a little more time to complete the additional information required
- In a small number of cases, funding of Ig therapy for certain medical conditions identified by clinical specialist groups will not continue, and more detail will be provided soon to help you to manage this with your patients
- There will be better guidance for patient eligibility and requirements to trial Ig therapy
- Formal review will always be needed to continue receiving Ig funded under the national blood arrangements
- Reporting of review outcomes is now enabled for all conditions
- Dosing will be more definitive
- BloodSTAR will be easier to use

The transition to Version 3 of the Criteria will include clear communication to doctors, nurses, patients and dispensers of Ig nationally. Starting in the next few weeks, the NBA will be communicating key messages and detailed information via email, system messaging, promotional material/flyers, companion guides, newsletters and in person at conferences and information sessions. Communication material will also be available for download from the NBA website.
For more information visit the new Criteria Version 3 page coming over the next few weeks.

BloodSTAR implementation in NSW

The implementation of BloodSTAR in NSW is now scheduled to occur in conjunction with the Version 3 Criteria on 22 October 2018. If you are in NSW and are involved in the prescription, use or management of immunoglobulin, you will soon be hearing how this will affect you and what you may need to do to get ready. The NBA is working closely with the NSW Ministry of Health and the Blood Service to make sure the transition to BloodSTAR is as smooth as possible.

BloodSTAR update released 1 July 2018

There are currently over 8,000 patients in BloodSTAR with active authorisations and approximately 8,500 registered users as Authorisers, Medical Officers, Nurses or Facility Administrators. The system continues to have high use with 627 initial authorisation requests and 10,431 dispense episodes of Ig in BloodSTAR nationally during June 2018. The NBA continues to work to improve its blood sector systems to ensure they meet the

requirements of end users efficiently and effectively. There is a new update of BloodSTAR which is targeted for release on Sunday 1 July 2018.
This update will include new functions and enhancements that will improve the usability and functionality of the system. Upcoming enhancements include:

- ability to extract treating medical specialists that are linked to active authorisations that may not have a BloodSTAR account
- display of additional information typed into the criteria manager for qualifying criteria during an authorisation request
- new sound-alike and keyword functioning for Medical Condition/Specific Condition/Indication search function when creating requests
- ability for prescriber to see relevant criteria above the evidence item on the electronic form
- improved search capabilities to improve results when searching for patients or medical conditions
- help menu including a frequently asked questions page
- news display on homepage
- link to support material and a Contacts page

For more information on BloodSTAR visit www.blood.gov.au/bloodstar.

Did you know?

Reminder to Medical Officers

Registering your specialty with AHPRA

Medical specialists must have their speciality registered with the Australian Health Practitioner Regulation Agency (AHPRA) for the Ig Governance Program to recognise the specialist qualification. BloodSTAR is linked to the AHPRA database, therefore if a clinician does not register all applicable specialist qualifications with AHPRA BloodSTAR will not be able to recognise that particular speciality for the clinician.
Visit http://www.ahpra.gov.au/registration.aspx(link is external) to check your registration details.

April 2018

Version 3 of the Criteria

The Ig Governance Program continues to focus efforts to implement Version 3 of the Criteria in BloodSTAR. All changes to the Criteria have now been approved by governments via the Jurisdictional Blood Committee. In the next few weeks, we will begin some internal work on entering Version 3 of the Criteria into BloodSTAR, although the changes will not be seen until it is released later this year.

There will be a number of changes to some of the Criteria conditions, such as adding or removing qualifying criteria or requiring different tests to qualify for immunoglobulin. The Ig Governance Program will work with health providers to ensure eligible patients are not disadvantaged by the changes.

The transition to Version 3 of the Criteria will include clear communication to doctors, nurses, patients and dispensers of Ig nationally. The NBA intends to communicate key messages via email, system messaging, promotional material/flyers, companion guides, newsletters and in person at conferences and information sessions. Communication material will also be available for download from the NBA website.

A summary of proposed changes (as at the last public consultation) that will be introduced for the Version 3 *Criteria* can be found here.

BloodSTAR

Since the national rollout in 2016 (except for NSW), BloodSTAR has been used successfully to manage immunoglobulin authorisation. There are currently 8,226 patients in BloodSTAR with active authorisations and 8,315 users as Authorisers, Medical Officers, Nurses or Facility Administrators. The system continues to have high use with 635 initial authorisation requests and 9,751 dispense episodes of Ig in BloodSTAR nationally during February 2018.

A new release of BloodSTAR (version 2.8) is planned in the coming months which will see a number of useability improvements and functionality to support release of Version 3 of the Criteria later this year. We'll inform users of the changes via email and newsletters.

For more information on BloodSTAR visit here.

BloodSTAR calculator for adjusting Ig dose for ideal body weight

BloodSTAR features a built-in calculator BloodSTAR for adjusting immunoglobulin dose for ideal body weight. Whilst this may be a useful tool for many patients, the tool is not suitable for patients aged less than 18 years, patients less than 152cm in height, patients that are pregnant, or patients that are underweight.
A warning message has been added to BloodSTAR to support clinicians when they are deciding whether or not to use the BloodSTAR Calculator.

A detailed description regarding the appropriate use of the calculator has been published on the NBA website accessed at https://www.blood.gov.au/bloodstar-calculator-adjusting-ig-dose-ideal-body-weight.

Performance Improvement

We are currently working on a Performance Improvement Strategy for the Ig Governance Program. The strategy will promote a nationally consistent approach to the management and use of immunoglobulin. This will be done by analysing BloodSTAR data and providing useful reports to doctors, nurses and other BloodSTAR users. These reports will also help to establish benchmarking activities, to encourage greater review of prescribing and/or product management practices.

Keep an eye out on the website for further news on the strategy.

Medical Officers - Did you know?

Registering your specialty with AHPRA
Medical specialists must have their speciality registered with the Australian Health Practitioner Regulation Agency (AHPRA) for the Ig Governance Program to recognise the specialist qualification. BloodSTAR is linked to the AHPRA database, therefore if a clinician does not register all applicable specialist qualifications with AHPRA BloodSTAR will not be able to recognise that particular speciality for the clinician.
Visit http://www.ahpra.gov.au/registration.aspx(link is external) to check your registration details.