Ig Governance Criteria and Progress Updates - 2019

July 2019

Version 3 of the Criteria

Version 3 of the Criteria for access to Ig under the national blood arrangements was implemented nationally on 22 October through BloodSTAR. Further information on Version 3 Criteria is available at https://www.blood.gov.au/igcriteria-version3.

The Ig Governance Program has received and responded to feedback relating to the new Criteria, which can inform further changes or future system requirements. A number of changes to the Criteria have been identified for consideration, and will follow a process for evolving the Criteria.

The Criteria for each medical condition can be printed from BloodSTAR or from www.criteria.blood.gov.au (link is external) if required, but any printed version must regularly be checked for currency.

BloodSTAR

BloodSTAR was fully implemented as a national system on 22 October 2018 and is now the sole channel for clinicians to seek authorisation for access to Ig products under the national blood arrangements, in accordance with the Criteria.

The NBA has continued to enhance BloodSTAR so that functionality supports the Criteria and the Ig Governance Program objectives in general, as well as improving usability for end users.

A new release of BloodSTAR (version 3.1) has been implemented which provides a number of useability improvements and functionality to support Version 3 of the Criteria. The new release covers enhancements to support:

- transitioning authorisations to the latest minor version of the Criteria;
- product allocation; and
- general system improvements and bug fixes.

BloodSTAR Statistics

There are currently over 13,700 patients in BloodSTAR with active authorisations and over 14,000 users as Authorisers, Medical Officers, Nurses or Facility Administrators.

There were 1004 initial authorisation requests and 17,359 dispense episodes of Ig in BloodSTAR nationally during June 2019.

Dose Rounding in BloodSTAR

When an Ig dose is requested in BloodSTAR the system automatically rounds the dose to fit the most appropriate Ig vial sizes. Generally the rounding is by a very small margin and improves the ease of dispensing and administration to patients. The requested dose is displayed to the prescriber, along with a message stating the rounded dose.

Once the request has been approved, only the rounded dose is visible on the treatment plan. The Medical Officer must continue to follow local requirements for prescription, dispensing and administration; this may be either the rounded dose, or the original requested dose if more appropriate.

As BloodSTAR authorisation is not a prescription for treatment, prescribers must consider which dose is most appropriate when completing a prescription following authorisation approval.

Health Technology Assessment of Ig use (Ig Reviews)

All Australian Governments, through the Jurisdictional Blood Committee (JBC), have agreed to conduct pilot Health Technology Assessments of Ig use for three conditions funded under the Criteria, to ensure government-funded use within Australia is based on evidence of clinical safety, effectiveness and cost-effectiveness.

The process for conducting the assessments has been based on the framework for conducting Post Market Reviews of medicines subsidised under the Pharmaceutical Benefits Scheme, with modification to allow evaluation of the evidence for each Ig indication by the Medical Services Advisory Committee (MSAC). The assessments will consider Ig use in the context of both intravenous and subcutaneous infusion where relevant.

Assessment has commenced on the following three medical conditions:

- Chronic inflammatory demyelinating polyneuropathy (CIDP);
- Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation; and
- Myasthenia gravis
- Outcomes of the assessments are expected in late November 2019 and will be provided to the JBC for consideration. Further information can be found
- at https://www.blood.gov.au/health-technology-assessment-reviews-immunoglobulin.

National Policy: Access to Government Funded Ig Products in Australia

An update to the *National Policy: Access to Government-Funded Ig Products in Australia* is being prepared to ensure it is up to date, and to provide clarification around roles and responsibilities, and access arrangements. The update to the policy will take account of the full implementation of BloodSTAR and the release of Version 3 of the Criteria, and will improve clarity, without any change of policy intent. NBA intends to publish the updated policy on the NBA website once finalised.

Performance Improvement and Knowledge Development

The NBA has developed a National Immunoglobulin Governance Performance Improvement Strategy (the Strategy) to monitor performance and promote continuous improvement across the Ig Governance arrangements.

The NBA has consulted with stakeholders and developed a list of activities for inclusion in the Strategy, which include:

- educational material – a range of education activities and resources that could support clinicians and others to undertake their roles and responsibilities under the National Policy;
- horizon scanning – options to ensure the NBA is well informed about upcoming issues, trends, advancements, policy changes, ideas, and events in relation to the use, management and governance of Ig products both domestically and internationally;
- addressing variation in Ig use – to better understand the reasons underpinning the variation and whether it represents appropriate clinical practice or requires more active management by the NBA; and
- auditing, reporting and identifying jurisdictional issues – a number of reporting activities are planned.

The NBA is working with BloodSafe eLearning Australia (BEA) to progress the development of an e-learning module on accessing Ig through national governance arrangements.

The NBA is also working with the Department of Health under the Value in Prescribing Program. Through this program, an external provider will be funded to deliver education tools and resources to support specialists to use Ig appropriately and in accordance with the National Policy and Criteria.

Data and Reporting

Having availability and access to quality data is crucial in analysing current usage pattern of Ig products and identifying areas of opportunity to make targeted improvements in an efficient and effective manner.

Sharing certain data is a useful tool for communicating with stakeholders about various aspects of performance. A number of data and reporting activities have been identified as priorities and will be a focus for NBA over the next six months. These activities will facilitate ongoing work within the Performance Improvement Strategy and include:

- establishing regular reporting (including extracts) to support Ig Governance Program activities;
- presenting a selection of high-level snapshot data regarding Ig use; and
- determining current user issues with governance arrangements and system via better internal reporting.

National Immunoglobulin Interest Group

The National Immunoglobulin Interest Group (NIIG) is still receiving nominations for representatives. The NBA intends to seek input from members into various Ig Governance matters as necessary. When the NBA has a specific need, NIIG members will be contacted via email with issues being discussed via teleconference if necessary.

If you would like to participate please let us know by providing your full name, facility name, position, contact phone number and email address to support@blood.gov.au(link sends e-mail). The NIIG is open to all those involved in the use and management of Ig and the NBA welcomes newcomers as well as experienced participants.

February 2019

Welcome to the latest edition of the Version 3 Criteria update newsletter - February 2019.

Version 3 Criteria

The *Criteria for the Clinical Use of Immunoglobulin in Australia* (the Criteria) changed to Version 3 in BloodSTAR on 22 October 2018. As is usual after a major change the National Blood Authority has received a variety of feedback from users and is working hard to provide clarification or implement improvements. This email provides some clarification for common questions relating to Version 3 Criteria.

Version 3 Criteria is available at www.criteria.blood.gov.au.

Transition Historical Review Questions

It is important that Ig therapy is directed to those patients where it is likely to be effective and who do not have safe alternative therapies. For many continuing authorisation requests for patients transitioning from Version 2 to Version 3 of the Criteria, medical officers will need to provide some additional historical information about the patient's diagnosis and initial response to Ig therapy in the form of Transition Review questions. This is to ensure patients transition appropriately to the right indication, and to ensure they are still eligible to receive Ig product under the new Criteria.

The transition review questions will appear **only once** for each patient who was previously approved for Ig therapy in Version 2. Many of the historical questions are non-mandatory or allow for medical officers to provide a responses indicating the result is not known or wasn't tested. In most cases a written description can be provided. We ask that medical officers provide the information where it is available, although it is recognised that some patients will have been diagnosed under a different specialist or some time ago and this information may not be readily accessible.

Mandatory and Non-mandatory Questions

While most questions in authorisation requests are mandatory, it is important to note that some are not. Mandatory questions are marked using a red asterisk (*) and BloodSTAR will not allow submission of a request to proceed if these are not completed. Where there is no red asterisk, a response is not mandatory and the submission can proceed.

Specialist and Consultation Requirements

It is a requirement, as outlined in the National Policy: Access to Government-Funded Immunoglobulin Products in Australia (National Policy) and the Criteria, that all patients in BloodSTAR must be treated by a medical specialist; this is called the **Treating Medical Specialist**.

Most conditions in Version 3 Criteria require a diagnosis or review by a particular type of specialist to access government-funded Ig. The National Immunoglobulin Policy requires all specialists to have their specialist qualification along with the Specialty Field of Practice registered with the Australian Health Practitioner Regulation Agency (AHPRA).

A consultation for diagnosis or review does not always need to take place face to face. A consultation with the appropriate specialist may occur by telephone, written correspondence or video-consultation. These arrangements can be particularly useful for patients who are not located in a metropolitan area so they can receive access to timely treatment.

Please note that it is at the discretion of the consulted medical specialist to accept responsibility for the diagnosis, review or prescription of Ig treatment for a patient. Medical officers completing the authorisation request (**Requesting Medical Officer**) will receive a warning if they have not selected the required specialist type before submitting. The consulted specialist must be nominated within BloodSTAR on the authorisation request as either:

- the **Treating Medical Specialist** (TMS), i.e. the patient's usual specialist;
- the **Diagnosing Medical Officer**, i.e. the consulted specialist who is responsible for ensuring diagnostic criteria is met (this may be the same as the TMS); or
- the **Reviewing Medical Officer**, i.e. the consulted specialist who participated in the clinical review of the patient (this may be the same as the TMS)

Changes to Specialist Requirements

There have been changes to the diagnosing or reviewing specialist type for some conditions Version 3 Criteria to access funded Ig. Medical officers completing the authorisation request will receive a warning if they have not selected the required specialist type before submitting.

Remember, you can consult the required specialist type for an Ig authorisation request using telephone, email, written correspondence or video-conferencing. This will reduce treatment delays waiting for appointments.

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.

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 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 government funded under the National Blood Agreement. Requests to access publicly funded immunoglobulin products in Australia must be authorised under the Criteria.

The changes to the Criteria will assist with meeting Standard 7 – Blood and Blood Products of the National Safety and Quality Service (NSQHS) Standards.

Where can I find more information?

Version 3 Criteria and supporting information is now available at www.criteria.blood.gov.au. Health professionals can view or print the Criteria by condition, check patient eligibility, review the assessment scales used for neurological conditions and check dosing with the dose calculator.

Detailed information about what changes have been made to the medical conditions within the Criteria is available on the website at www.blood.gov.au/igcriteria-version3. Health professionals can view or print the following:

- Summary of changes by the specialty
- Individual condition factsheets outlining the changes
- Individual conditions as they will appear in the Version 3 Criteria

January 2019

Version 3 of the Criteria has been released!

Version 3 of the Criteria was successfully released into BloodSTAR on 22 October 2018.

Developed by clinical working groups and in collaboration with relevant clinical colleges and societies, Version 3 of the Criteria aims to more clearly articulate and standardise diagnostic, qualifying and review requirements. More comprehensive justification and evidence from clinicians will be required to confirm patient eligibility and so will strengthen the capacity to direct Ig product to those who most require it. National funding of Ig products is no longer supported for a small number of low-use conditions as better alternative treatments are available.

The Criteria is available at www.criteria.blood.gov.au

The Criteria for each medical condition can now be printed from BloodSTAR or from www.criteria.blood.gov.au if required, but any printed version must regularly be checked for currency. The NBA will no longer publish the Criteria in hard-copy.

BloodSTAR is now live Australia-wide!

BloodSTAR is now a national system following implementation in NSW from 22 October 2018.

BloodSTAR is the sole channel for doctors in Australia to seek authorisation for the prescription of Ig products in accordance with the Criteria.

The key benefits of BloodSTAR as a national system are:

- ensuring the consistency of processes and application of the Criteria so that Ig products are directed, based on best evidence and clinical opinion, to patients who are most likely to benefit and for whom there are no safe and effective alternative treatments
- consistently promoting the clinical review of ongoing patients, and consideration of alternative therapies, where appropriate as identified in the Criteria
- support for patients across multiple sites
- better flexibility for managing mobile or remote patients, and
- generation of information for:
- supply planning and management
- supply risk management
- process and system governance and improvement
- potential linkage with research, and
- further development of the Criteria to ensure Ig is directed to where there is evidence of greatest benefit.

BloodSTAR statistics

There are currently over 13,900 patients in BloodSTAR with active authorisations and approximately 12,800 users as Authorisers, Medical Officers, Nurses or Facility Administrators. The system continues to have high use with 857 initial authorisation requests and 16,251 dispense episodes of Ig in BloodSTAR nationally during October 2018.

National Policy: access to government funded Ig products in Australia

The *National Policy: Access to Government-Funded Immunoglobulin (Ig) in Australia* (National Policy) sets out the process that must be followed and describes the rules and requirements that must be complied with to access Ig products under the National Blood Agreement. Together with the Criteria and BloodSTAR, the National Policy has standardised processes nationally to improve equitable access to government funded Ig products.

The policy is undergoing revision to align with changes that have been made to BloodSTAR since its implementation in 2016, and Version 3 of the Criteria. It also aims to make more direct statements of responsibilities, and corrects guidance that has become outdated including changes to external document titles and web links.

The updated National Policy will be available soon.

Module 2 of the Managing Blood and Blood Product Inventory Guidelines

Module 2 of the Managing Blood and Blood Product Inventory Guidelines (managing IVIg and SCIg) has been updated, and is available at https://www.blood.gov.au/module-2-ig-inventory-management-guidelines.

The purpose of this Module is to assist health providers in meeting the requirements of the National Policy by:

- describing how to establish and manage stock levels
- outlining the Ig product ordering models
- identifying different methods to determine ordering requirements/trigger
- providing recommendations for good practice

Performance Improvement and Knowledge Development

The implementation of BloodSTAR and Version 3 of the Criteria are significant achievements and have been the main focus for the Ig Governance Program for some time. Focus can now shift to other Ig Governance Program activities, including progressing the development of a Performance Improvement Strategy. The strategy promotes a nationally consistent approach to the management and use of immunoglobulin. One way this can be done is 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.

The Ig Governance Program will also work with doctors, nurses, patients and other relevant stakeholders to develop a suite of educational materials for clinicians and patients.

Keep an eye out on the website for further news on future Ig Governance Program activities.

National Immunoglobulin Interest Group

The NBA has established the National Immunoglobulin Interest Group (NIIG). The main aim of this national group is to provide the NBA with ongoing feedback and input in relation to updates and proposed changes to the Ig Governance Program and the BloodSTAR system from stakeholders involved in the use of immunoglobulin across Australia. Thank you to those who have already expressed their interest in participating in this group. The NBA would like to ensure widespread representation for this group including medical officers, nurses, dispensers (pathology and/or pharmacy) and facility administrators.

The NBA intends to engage regularly with the NIIG and email updates on Ig Governance Program activities. The NBA will also seek input into various Ig Governance matters as appropriate. When there is a specific need, the Ig interest group will be contacted via email with issues being discussed via teleconference if necessary.

The NIIG will complement the national network of committees involved in the Ig Governance Program, including jurisdictional Ig ‘user groups’, Specialist Working Groups for Immunology, Neurology, Haematology and Transplantation, the National

Immunoglobulin Governance Advisory Committee and the Jurisdictional Blood Committee. The NIIG will also facilitate the circulation of updates, analysis and news of better practice initiatives within this overall network.

If you would like to participate please let us know by providing your full name, facility name, position, contact phone number and email address to support@blood.gov.au(link sends e-mail).