Ig Governance Criteria and Progress Update - 2017

(Only one Update was published in 2017)

August 2017

Public Consultation on proposed change to the *Criteria for the Clinical Use of Immunoglobulin in Australia*

Public Consultation on proposed changes to the *Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia* (the *Criteria*)– Closed on 9 June, 2017.

The Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia (the *Criteria*) have been developed by the National Blood Authority using expert Specialist Working Groups of clinicians to identify the medical conditions and circumstances for which immunoglobulin product is supplied and funded by governments under the national blood arrangements.

Public consultation on the most recent round of proposed changes to the *Criteria* closed on Friday 9 June 2017. Feedback has been considered by the National Blood Authority and the proposed changes were endorsed by the National Immunoglobulin Governance Advisory Committee at their quarterly meeting in July 2017. The proposed changes will be presented to the Jurisdictional Blood Committee for consideration on behalf of funding governments in September 2017.

These proposed changes, which aim to more clearly articulate and standardise the diagnostic, qualifying and review criteria, are required to assist with managing the growth in demand for this precious, human-derived product by ensuring it is only used for clinically appropriate purposes.

The 2017 consultation process supplements the consultation process undertaken in 2015 when the NBA sought feedback on conditions listed in Chapter 5 - *Established Therapeutic Role and Chapter 6 – Emerging Therapeutic Role of the Criteria.*

The 2017 public consultation related to the proposed changes to access criteria for all conditions listed in Chapter 7 - *Exceptional circumstances only* and Chapter 8 - *Not supported*. Also included in that round of public consultation were a small number of

conditions listed in *Emerging therapeutic role* where further proposed changes were recommended since the public consultation in 2015.

With the exception of NSW, all States and Territories in Australia access Ig through the new online system BloodSTAR. The access criteria in BloodSTAR are aligned with those published in *The Criteria for the Clinical Use of Immunoglobulin in Australia* (Second Edition) 2012 (the*Criteria*). The BloodSTAR criteria are referred to as 'Version 2.1 Criteria' or v2.1. and this will be updated to Version 3 or V3 when the revised *Criteria* has been implemented. The National Blood Authority will also communicate approved changes and any actions that might be required to all key stakeholders well in advance of the changes being implemented.

When will Version 3 of the *Criteria* be available?

The Criteria is currently undergoing a third review by Specialist Working Groups (SWGs) in Neurology, Haematology, Immunology and Transplantation.

Public consultation on the proposed Chapter 5 and 6 changes to the *Criteria* closed at 5pm on Monday 27 July 2015. The SWGs reviewed all submissions and revised the *Criteria* as necessary before submission to the National Immunoglobulin Governance Advisory Committee (NIGAC) in November 2015. NIGAC endorsed the changes which were presented to the Jurisdictional Blood Committee for endorsement. The Jurisdictional Blood Committee approved these changes in 2015.

The SWGs are currently addressing conditions in Chapters 7 and 8. The approach being undertaken includes:

- A brief review of recent literature to confirm the status of evidence supporting the use of IVIg in the condition
- Draft the justification for evidence and diagnostic description sections
- Develop qualifying and review criteria and define appropriate evidence items, parameters and authorisation values
- Define the length of treatment and dosing types/ ranges to be used.

Public consultation on proposed changes to the *Criteria* was open from 15 May to 9 June, 2017. These changes, which aim to more clearly articulate and standardise the diagnostic, qualifying and review criteria, are required to restrain the unsustainable growth in demand for this precious, human-derived product. The 2017 public consultation relates to the proposed changes to access criteria for all conditions listed in Chapter 7 - Exceptional circumstances only and Chapter 8 - Not supported. Also included in that round of public

consultation were a small number of conditions listed in Emerging therapeutic role where further proposed changes have been recommended since the public consultation in 2015.

The Chapter 7 and 8 changes will be presented to the Jurisdictional Blood Committee for endorsement in September 2017, and be available for the release of the *Criteria*, third edition in BloodSTAR in 2018.

BloodSTAR

From July 2016, the national roll out of BloodSTAR commenced using a staggered jurisdictional approach. This is a move away from paper based request forms to using the online BloodSTAR system. With the exception of NSW, all states and territories in Australia now access Immunoglobulin through BloodSTAR. The scheduled date for BloodSTAR implementation in NSW is yet to be advised.

The access criteria in BloodSTAR are aligned with those published in the *Criteria* for the Clinical Use of Immunoglobulin in Australia (Second Edition). An adaptation of the second edition of the Criteria is applicable in BloodSTAR for all states except NSW. The BloodSTAR criteria are referred to as 'Version 2.1 Criteria' or v2.1.

The *Criteria* as they appear in BloodSTAR can be viewed here.