

Adaptation of *the Criteria* for BloodSTAR

Background

The Criteria

In common with many other examples of high cost interventions, there has been significant focus to ensure that eligibility for access to IVIg funded under the National Blood Arrangements is appropriate. The evidence based [Criteria for the Clinical Use of Intravenous Immunoglobulin \(IVIg\) in Australia](#) (*the Criteria*) was first published 2007 to assist clinicians and transfusion medicine professionals to identify the conditions and circumstances for which the use of intravenous immunoglobulin (IVIg) is appropriate and funded under the National Blood Agreement. The Criteria have been strengthened and reviewed in 2012 (Version 2) and further checks and balances are in place with ordering through the Blood Service providing an additional gatekeeper step to confirm that requests are appropriate.

In addition, the National Blood Authority (NBA) Specialist Working Groups (SWGs) have commenced a review of *the Criteria* to Version 3. This provides much more detail around qualifying criteria, and evidence required to support any claim against the criteria.

BloodSTAR

[BloodSTAR](#) (Blood System for Tracking Authorisations and Reviews) is the new online system developed by the NBA on behalf of all Australian Governments to supports health providers in managing their Ig Governance obligations as set out in the [National Policy: Access to Government Funded Immunoglobulin Products in Australia \(The National Policy\)](#).

The system standardises and manages access to the supply of immunoglobulin products for the treatment of conditions identified in the *Criteria*, funded by all governments through the national blood arrangements. With the move to this new online system, *the Criteria* will no longer be published in a documented publication, and will be contained within the system, accessible via a public website. This allows for more dynamic changes to *the Criteria* in the future, meaning that governments can respond more appropriately to emerging evidence concerning the use and benefits of Ig.

BloodSTAR replaces the Australian Red Cross Blood Service (Blood Service) system STARS which has been used for a number of years to manage the authorisation and review obligations. The Blood Service transfusion medicine specialist team continue in their role as authoriser of Immunoglobulin Access Requests, with BloodSTAR extending system capability to prescribers, nurses/midwives and dispensers, closing the information loop on the delivery of care to patients.

The launch of BloodSTAR formally occurs in 2016, with a transition period until the end of 2016 as each Australian state and territory implement the system through a staggered roll-out. Prescribers, authorisers and nurses will access BloodSTAR through a web interface that is reached through the NBA's [BloodPortal](#). Dispensers will access the system through a new Authorisation module in [BloodNet](#).

Adapting the *Criteria*

The go-live system is based on an adaptation of the criteria Version 2 and the current request forms. The adaptation has been required because there were certain fields in the system that could not be populated directly from Version 2 either because they were absent or ambiguous, or only referred to indirectly. This is particularly the case for review criteria.

In many instances, to allow prescribers to conduct a review within BloodSTAR, there must be an initial qualifying value, which is entered at the initial authorisation request. Where review or other criteria were inferred in Version 2 and the detail was available from Version 3 the information from Version 3 has been used to populate the required fields in BloodSTAR.

Evidence items

The evidence items fields are available in the system for one of four reasons:

- To capture data or values (such as platelet count or IgG level) that are currently collected on the paper request forms,
- To clarify qualifying criteria where the published version is silent or ambiguous (such as words like thrombocytopenia or recurrent),
- To assist prescribers with baseline values they may like to compare at review, or
- To assist in data analysis to inform future criteria access arrangements or development of the system.

During the BloodSTAR transition period (July to December 2016), the addition of 'new' Criteria 'evidence items' fields should not change the basis for approval of authorisation of Ig product. Authorisers will evaluate authorisation requests with the same approach that applies to authorisation based on the use of previous paper forms. This means that where evidence items are not completed or have caused the system to 'decline', and if those values would not have been required on the paper request form, they should not disqualify access (and the Blood Service authoriser should override the system determined result if necessary).

After the transition period, requests will be evaluated with a stricter approach, and assessment of evidence items will start to be applied. This will be the subject of further communications and specific training and protocols within the Blood Service, the NBA and wider stakeholders.