Strengthening the Criteria

Jo Cameron
Director, Immunoglobulin Governance
The National Blood Authority
NICE 2017
What is the Criteria?

- 1st published 2007
- Describe eligibility criteria that patients must meet to receive Ig that is funded by all Australian governments
  - Conditions for which Ig has an established therapeutic role (previously Chapter 5)
  - Conditions for which Ig has an emerging therapeutic role (previously Chapter 6)
  - Conditions for which Ig use is in exceptional circumstances only (previously Chapter 7)
  - Conditions for which Ig is not supported (previously Chapter 8)
National Online System for Tracking Authorisations and Reviews

- Standardises and manages access to Ig products consistent with Criteria
- Introduced in 2016

What is BloodSTAR?
Demand for precious high cost product continues to grow at around 12% p.a.

Why is the Criteria being revised?

Strengthening the *Criteria* will help to ensure:
- Ig products are prescribed consistently in line with current evidence and expert opinion;
- sustainability of Ig supply, ensuring it is used where it’s needed most with the greatest benefit; and
- ethical expenditure of government funds in accordance with relevant national safety and quality standards for health care.
How is the Criteria being revised?

- Partially reviewed in 2012
- Complete review commenced 2014
- Specialist Working Groups review evidence and propose revisions
- Complete redevelopment of all qualifying, review and dose criteria, evidence items and system controls
- Public consultation allows feedback
- Endorsed by NIGAC and JBC

The revision process commenced in early 2015 and has involved 55 meetings of the SWGs.

- 17 Neurology SWG meetings
- 16 Immunology SWG meetings
- 13 Haematology SWG meetings
- 9 Transplantation SWG meetings
What is changing?

- May ask for more clinical information (such as pathology results) to confirm the diagnosis and requirement for Ig therapy.
- Prescribers may need to provide information regarding the patient’s response to Ig therapy at review.
- Some conditions will now require patients to be diagnosed by a particular type of specialist (e.g. Immunologist) with ongoing therapy approved when the specialist is consulted.
- Some patients may need to see their specialist more frequently to ensure they are responding to Ig therapy.

The changes to the Criteria will more clearly articulate and standardise the diagnostic, qualifying and review criteria, initial and continuing periods, dosing controls and supporting evidence for access to publicly funded Ig.

This is to ensure that Ig products are only used for clinically appropriate purposes for the treatment of patients whose health is most likely to be improved with Ig therapy, and will assist with consistence of access and managing the growth in demand for this precious human derived product.
What needs to Transition?

**BLOODSTAR STATISTICS**

- Number of patients requiring Ig treatment in 2016: 16,500
- Number of users registered in BloodSTAR: 10,000
- Number of conditions listed in the Criteria: 54
- Number of indications listed in the Criteria: 109
- Number of data entry points required to be built in BloodSTAR to allow transition: 22,000
Existing patients need to transition from 89 indications within 61 medical conditions to 109 indications in 54 conditions

1. New initial authorisation – will commence with V3 in BloodSTAR from the implementation date;
2. Existing authorisations with no option for ongoing Ig therapy - will expire on V2.1 at the end of the current authorisation;
3. Existing authorisations with an option for review and ongoing therapy:
   a. minor change/s to qualifying or review criteria where intent remains the same - will be moved to V3 from the implementation date. There may be additional questions at the first review for some indications to capture new evidence that would be otherwise required at qualifying.
   b. changes to qualifying or review criteria where additional information is required - patient authorisations will move to the V3 indication at the next review with the prescriber selecting the new V3 indication, providing additional evidence in BloodSTAR and/or providing additional evidence to Authorisers.
Want more information?

- What is changing
- Why is it changing
- What you need to know
- What needs to be done differently

For more information please visit: blood.gov.au/lg-program-updates

ph 13 000 BLOOD