NATIONAL BLOOD AUTHORITY
AUSTRALIA

Approach to the Adaptation of *the Criteria* for BloodSTAR

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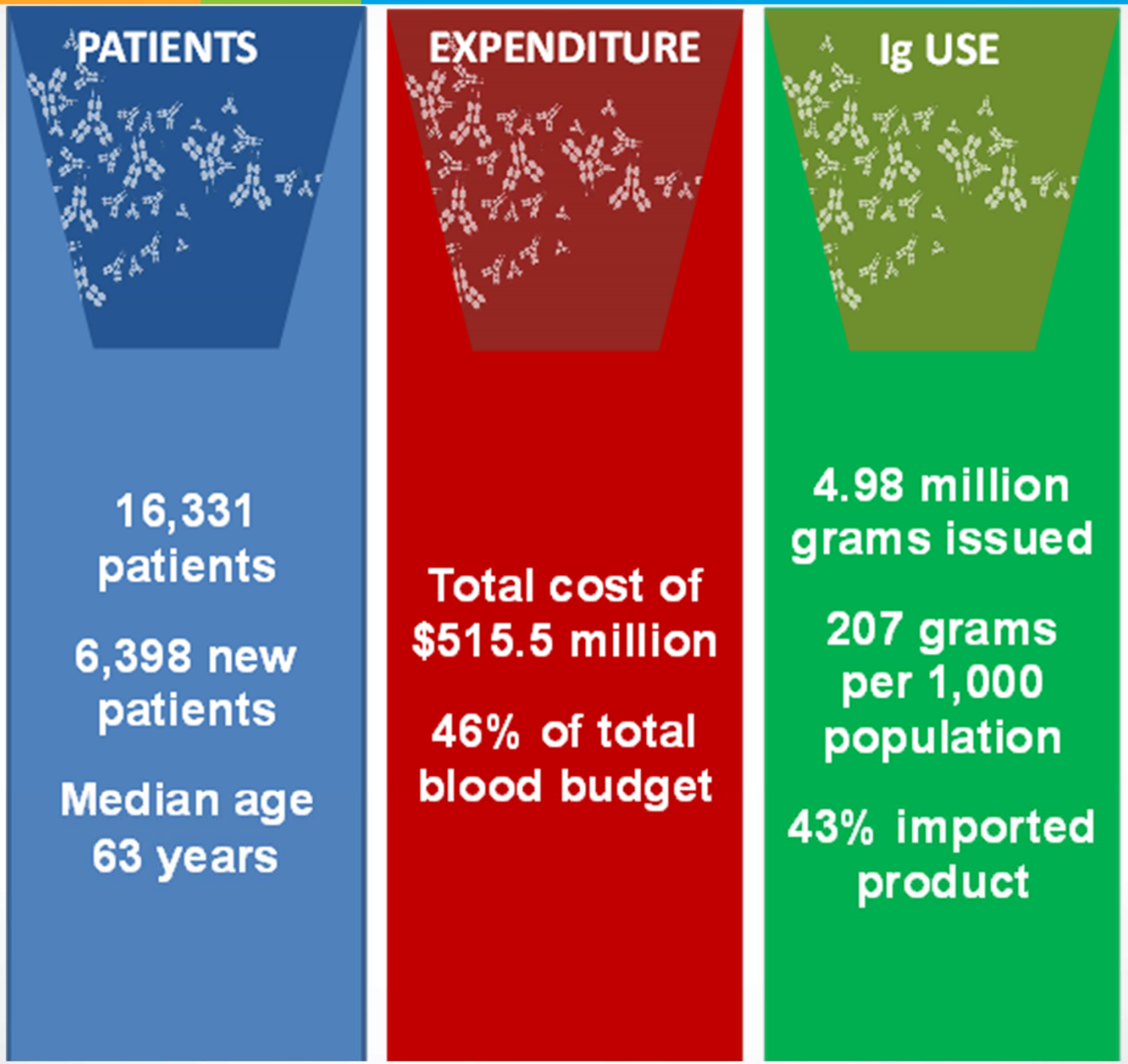
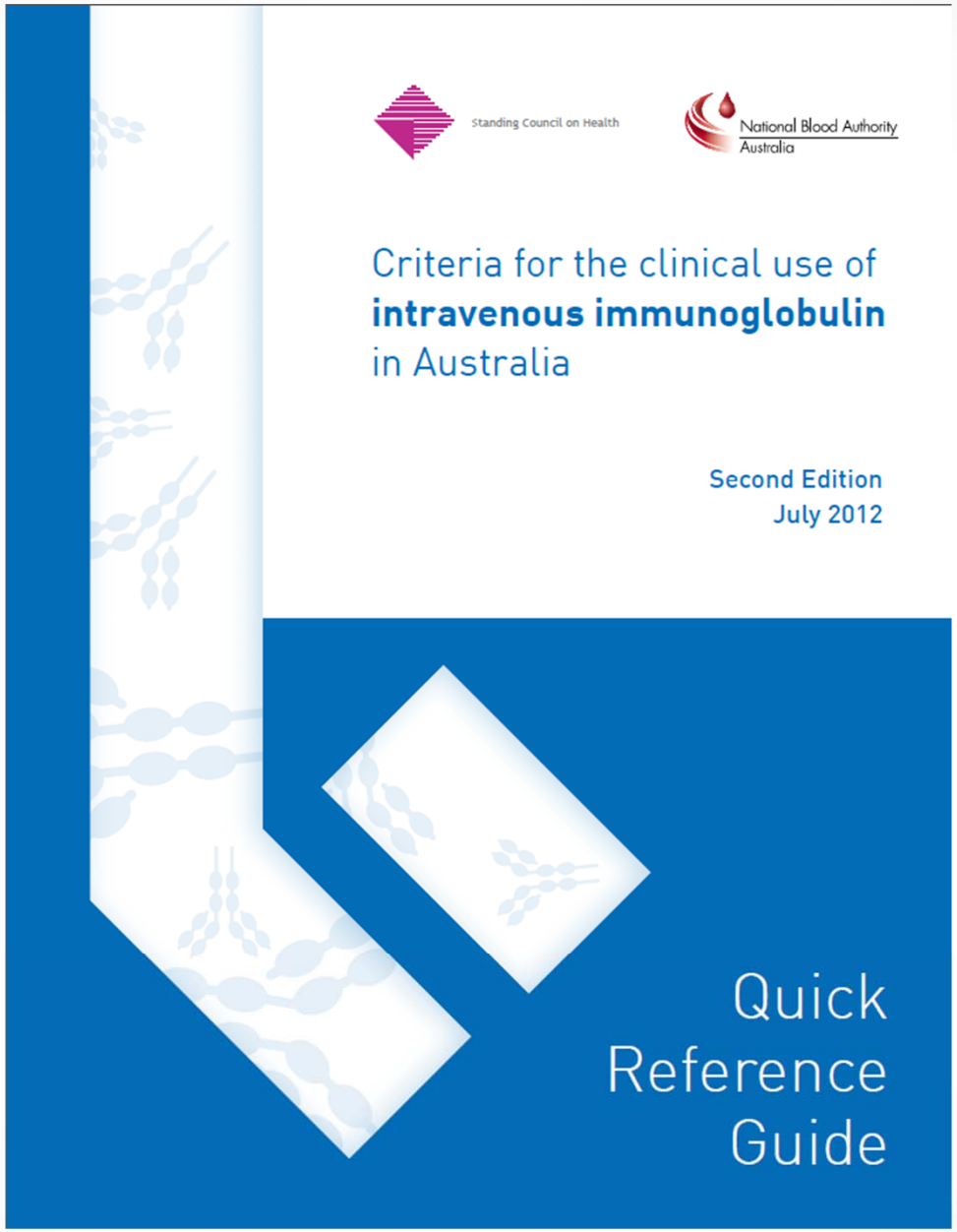
National Blood Authority
NICE 2016


PATIENTS
16,331 patients
6,398 new patients
Median age 63 years
EXPENDITURE
Total cost of $515.5 million
46% of total blood budget
Ig USE
4.98 million grams issued
207 grams per 1,000 population
43% imported product


Standing Council on Health
National Blood Authority Australia
Criteria for the clinical use of
intravenous immunoglobulin
in Australia
Second Edition
July 2012
Quick
Reference
Guide

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The Criteria

IVIg is a precious biological product, 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 *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.

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The Categories

Chapter 5
- Conditions for which IVIg has an established therapeutic role

Chapter 6
- Conditions for which IVIg has an emerging therapeutic role

Chapter 7
- Conditions for which IVIg use is in exceptional circumstances only

Chapter 8
- Conditions for which IvIg is not supported

For conditions not described in Categories 5-7 above, approved recipients may obtain IVIg via the Jurisdictional Direct Order component of the IVIg Standing Offer arrangement.

BloodSTAR is the new online system that will facilitate authorisations, dispensing and reviews of immunoglobulin products such as IVIg and SCIg. A national roll out of BloodSTAR will commence in July 2016

Ig Governance

Criteria for Clinical Use of Immunoglobulin in Australia

Reference Number

Browse the Criteria for Use | Check Eligibility | Dose Calculator

Ig Governance

Welcome to Ig Governance - *Criteria for the clinical use of intravenous immunoglobulin in Australia* (Criteria).

The Criteria has been developed by governments to identify the medical conditions and circumstances for which immunoglobulin product is supplied and funded by governments.

Please note that this site is not intended as a clinical practice guideline and should not be used as a substitute for expert medical guidance and advice.

About Ig Governance

About the Criteria

Browse the Criteria for Use

View all medical conditions and circumstances where immunoglobulin product is supplied and funded by governments.

Check Eligibility

Follow a guided process to understand the eligibility requirements for medical conditions identified in the Criteria where access to government funded immunoglobulin product is supplied.

Dose Calculator

This tool will assist with immunoglobulin dosing by medical condition, as recommended in the Criteria.

Medical condition	Acquired **hypogammaglobulinaemia secondary to haematological malignancies chronic lymphocytic leukaemia (CLL), multiple myeloma (MM), non-Hodgkin lymphoma (NHL) and other relevant malignancies, and post-haemopoietic stem cell transplantation (HSCT)**
Qualifying criteria for IVIg therapy	Diagnosis of acquired hypogammaglobulinaemia secondary to haematological malignancies or stem cell transplantation with: • Recurrent or severe bacterial infection(s) and evidence of hypogammaglobulinaemia (excluding paraprotein); OR • Hypogammaglobulinaemia with IgG <4 g/L (excluding paraprotein). **Note:** For data tracking purposes, the type of malignancy being treated should be recorded with each request for IVIg.

Acquired hypogammaglobulinaemia secondary to haematological malignancies chronic lymphocytic leukaemia (CLL), multiple myeloma (MM), non-Hodgkin lymphoma (NHL) and other relevant malignancies, and post-haemopoietic stem cell transplantation (HSCT)

Conditions for which IVIg has an established therapeutic role.

Next Medical Condition >

Qualifying Criteria for IVIg Therapy

Prevention of recurrent bacterial infections due to hypogammaglobulinaemia associated with haematological malignancies.

- Recurrent or severe bacterial infection(s).

  AND

- Evidence of hypogammaglobulinaemia (excluding paraprotein).

OR

- Hypogammaglobulinaemia with IgG <4 g/L (excluding paraprotein).

Antibiotic therapy may be indicated in addition to immunoglobulin therapy.

Prevention of recurrent bacterial infections due to acquired hypogammaglobulinaemia secondary to stem cell transplantation for haematological malignancies.

- Recurrent or severe bacterial infection(s).

  AND

- Evidence of hypogammaglobulinaemia (excluding paraprotein).

OR

- Hypogammaglobulinaemia with IgG <4 g/L (excluding paraprotein).

Antibiotic therapy may be indicated in addition to immunoglobulin therapy.

A recent systematic review and meta-analysis of patients undergoing haemopoietic stem cell transplantation (HSCT) (60 trials, >4000 patients) reported an increased risk of veno-occlusive disease with no survival benefit, particularly in studies conducted since 2000. The authors concluded that routine prophylaxis with IVIg is not supported, but suggest that its use may be considered in lymphoproliferative

Supporting Evidence

Number of serious or recurrent infections in the last twelve months

5 bacterial infections in last twelve months

Severity of the most serious infections in the last twelve months

- [x] Life-threatening infection
- [ ] Suppurative lung disease and/or active bronchiectasis
- [ ] Sepsis
- [ ] Meningitis or brain abscess
- [ ] Pneumonia
- [ ] Suppurative bronchitis in a child
- [ ] Bone or joint infection
- [ ] Recurrent suppurative otitis media
- [ ] Recurrent suppurative sinusitis
- [ ] Infection requiring hospitalisation
- [ ] Other, please specify in comments

Comments

Please describe the most serious infection(s) and antibiotic or other treatment(s) required

Hospitalised requiring IV antibiotics twice

Serum IgG level (excluding paraprotein)

2.4 g/L

Date of assessment

07-Oct-2016

Interpretation of Results

Less than normal range for age

Upload results

Select files...

During the BloodSTAR transition period, the addition of ‘new’ Criteria ‘evidence items’ fields does 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.

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Q&A

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Saving & improving Australian lives through a world class blood supply

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Thank you

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