NATIONAL BLOOD AUTHORITY
AUSTRALIA

STRENGTHENED IMMUNOGLOBULIN PRODUCT AUTHORISATION AND MANAGEMENT

FREQUENTLY ASKED QUESTIONS

Current as at 24 October 2014

Contents

Strengthened Immunoglobulin Product Authorisation and Management

Key Changes - effective from 5 November 2014

1. **New Intravenous Immunoglobulin (IVIg) and Subcutaneous Immunoglobulin (SCIg) Authorisation Request Forms**

   - for all states and territories other than Western Australia
   - existing Australian Red Cross Blood Service IVIg and SCIg Order Forms will not be accepted except in Western Australia
   - patient (or parent/carer/guardian) explicit consent to the collection, retention and use of their personal sensitive data, must be confirmed
   - both pages of the Authorisation Request Form need to be completed and submitted to the Authoriser to enable assessment

2. **Standardised Patient Treatment Review Process and forms**

   - new Patient Treatment Review Outcome Notification Forms for all states and territories other than Western Australia
   - outcomes must be provided to the Authoriser within one month of the patient review date
   - patient weight will be required to support the requested dosage
   - patient (or parent/carer/guardian) explicit consent to the collection, retention and use of their personal sensitive data must be confirmed if this has not been provided in the last 12 months
   - access to the continuing supply of product will be ceased if the patient treatment review outcomes notification is not received by the Authoriser within one month of the patient review date
   - a transition period will apply for patients due for review during the three months from 5 November 2014 to allow for the introduction of the new forms.

Key Changes - for progressive implementation between 5 November 2014 and February 2016

3. **Coordinated in-hospital product ordering and management**

   - there is no requirement to change existing product ordering arrangements on 5 November 2014
   - in-hospital product ordering and management should transition towards being coordinated centrally by the dispenser role with responsibility for product inventory management
   - only Dispensers will have access to the Ig System (an online product authorisation and management database currently in development) for immunoglobulin product ordering, once it is implemented in February 2016
   - the Australian Red Cross Blood Service will assist facilities to transition to the new arrangements.

Frequently Asked Questions

1. Why has the *National Policy: Access to government funded immunoglobulin products in Australia* been developed?

The National Policy clarifies the roles and responsibilities of all stakeholders involved in the management of immunoglobulin, including:

- the provision of information required to support initial and ongoing therapy,
- standardised national patient treatment review process with revised forms, correspondence, and timeframes for providing information to support access requests for ongoing therapy, and
- coordinated in-hospital product ordering and management to improve transparency of product inventory, ensure that product is provided to authorised patients only, and to reduce expiry related wastage.

It is one of a number of measures being developed and implemented under the Immunoglobulin Governance Program, endorsed by all governments, to improve the governance and management of government funded immunoglobulin products. These measures are being implemented to ensure sustainability of immunoglobulin products into the future.

2. Why is the National Policy not being implemented in Western Australia on 5 November 2014?

While WA Health agrees with the overarching principles of the National Policy, it is still considering its position.

3. Where do I get the new authorisation request forms?

The six new Authorisation Request Forms (initially for all states and territories other than Western Australia) are available on the National Blood Authority website via this link, http://www.blood.gov.au/immunoglobulin-ig-governance-program.

Western Australia will continue to use the IVIg and SCIg Order forms available on the Australian Red Cross Blood Service website at http://www.transfusion.com.au/resource_centre/forms.

4. Do new authorisation request forms need to be completed for existing patients?

A new authorisation request form does not need to be completed for patients who are currently authorised, unless there has been a change to the patient's condition that requires a change in dose

and/or frequency. Requests for authorisation for new patients (from 5 November 2014) will need to be submitted using the new form.

5. Is more information being collected about individual patients?

The amount of information collected about an individual patient for the purposes of assessing authorisation against the *Criteria for the clinical use of intravenous immunoglobulin in Australia* 2012 is unchanged from existing arrangements.

6. Why do I need to confirm that the patient has provided their consent to the collection, retention and use of their personal sensitive data at the time of requesting patient specific authorisation for access?

Confirmation that the patient has provided their explicit written or oral consent to the collection, retention and use of their personal sensitive data is a requirement under Australian Privacy Principle 3 (APPs), in the *Privacy Act 1988 (Cth).* Under the Act, patients must provide their consent for the collection of their personal health information, and be informed about what their information is being used for and usual disclosures. The new Australian Privacy Principles came into effect in March 2014, and apply to both public and private organisations.

7. Does the Prescriber acknowledgement and confirmation page of the Authorisation Request Form have to be completed?

Yes, the prescriber is required to confirm that the patient has provided their explicit (written or oral) consent to treatment with immunoglobulin products and the collection, retention and use of their personal sensitive data. This is to ensure compliance with the National Safety and Quality Health Service (NSQHS) Standard 7 and the Australian Privacy Principles (APPs). This must be completed and submitted to the Authoriser to enable assessment of authorisation.

8. What if my patient does not consent to the collection, retention and use of their personal sensitive data?

If a patient does not consent to the collection, retention and use of their personal sensitive information, it will not be possible to authorise supply of Ig product for that patient, under the national blood arrangements. This is to ensure compliance under the Australian Privacy Principles (APPs) and National Safety and Quality Health Service (NSQHS) Standard 7.

The primary purpose of collection of this information is to uniquely identify individuals for assessment of authorisation for initial access and continuing access (where relevant).

Patients (and/or their parents/carers/guardians) who choose not to consent may access immunoglobulin products either as a Private Order or Jurisdictional Direct Order, made directly with the imported immunoglobulin suppliers.

9. Where do I send the new authorisation request form, once complete?

As currently occurs, authorisation request forms will be submitted to the local Australian Red Cross Blood Service other delegate responsible for assessing authorisation against the *Criteria for the clinical use of intravenous immunoglobulin in Australia 2012*. When you select your state or territory on the form, the contact details will automatically populate. For South Australian forms, the relevant hospital must also be selected.

10. Do I have to complete the Authorisation Request Form electronically?

The form can be completed electronically or it can be printed and completed. Please note the state or territory must be selected prior to the form being printed, as this populates the contact details for the appropriate Australian Red Cross Blood Service or other delegate responsible for assessing authorisation. The form must be printed and signed before being submitted.

11. Do I need to seek consent from all my patients regarding their personal sensitive data that was collected at the time they were previously authorised for access to government funded immunoglobulin products?

You will not need to contact and seek consent from patients who have been previously authorised to receive government funded immunoglobulin products for their existing condition. Patient consent will be sought at the time of the next review date for patients requiring continuing treatment.

A transition period will apply for three months from 5 November to allow time for the new Patient Treatment Review Outcome Notification Forms to be introduced. If you have been sent an old Patient Treatment Review Outcome Notification Form that does not include the Prescriber acknowledgement and confirmation of patient consent, please complete and return the form you have in hand.

12. What does 'coordinated in-hospital product ordering and management' mean?

Immunoglobulin product ordering and management should be coordinated within the hospital Dispensary (blood bank, pathology laboratory, pharmacy) or other delegate responsible for the management of blood and blood products. This may also be managed by multiple sites within the hospital, for instance subcutaneous immunoglobulin (SCIg) product ordering and management may be managed by the hospital pharmacy and intravenous immunoglobulin product ordering and

management may be managed by the hospital blood bank. Coordinated in-hospital product ordering and management is to ensure product transparency, accountability for dispensing product, and maintain traceability.

13. Does coordinated in-hospital product ordering and management need to be implemented from 5 November 2014?

Coordinated in-hospital product ordering and management will be implemented as a phased approach, with the expectation that it will be fully effective for the introduction of the Ig System in early 2016. The Ig System is a national immunoglobulin product ordering and outcomes database which is currently in development.

During the transition period, before the Ig System is implemented, it is important to prepare Dispensers for the changes that will be introduced with implementation of the Ig System, as it will only be Dispensers who will have access to the Ig System for the purposes of ordering product.

The Australian Red Cross Blood Service will liaise with facilities to assist with implementation of the required changes.

14. Will coordinated in-hospital product ordering and management affect current laboratory arrangements for product ordering in my hospital?

If a hospital laboratory is currently ordering immunoglobulin product as stock orders, or as patient specific orders, based on clinical demand for authorised patients, these arrangements will remain unchanged at the current time.

15. Do product orders have to be submitted through BloodNet from 5 November?

Ideally, product orders will be submitted by the Dispenser through BloodNet. Where BloodNet is not available and/or alternate arrangements are in place then these can continue. However, during the transition period, Weekly Order Sheets prepared by the wards should begin to be sent to the Dispenser, to improve visibility of product demand and management. This is to ensure that current inventory holdings are taken into consideration before more product is ordered, to reduce stock-piling and wastage.

It is important that Dispensers are prepared in advance for the changes that will be introduced with implementation of the Ig System in early 2016, as it will only be Dispensers who will have access to the Ig System for the purposes of ordering product. The Ig System is a national immunoglobulin product authorisation and outcomes database which is currently in development.

16. Are the Australian Red Cross Blood Service Weekly Order Sheets still allowed to be used by the wards from 5 November 2014?

During the transition period, Weekly Order Sheets prepared by the wards should begin to be sent to the Dispenser, to improve visibility of product demand and management. This is to ensure that current inventory holdings are taken into consideration before more product is ordered, to reduce stock piling and wastage. This is preparing hospitals for the changes that will become effective with the implementation of the Ig System as it will only be Dispensers who will have access to the Ig System for the purposes of ordering product.

The Ig System is an online product authorisation and management database which is currently in development. It will include a patient registry to enable the association of authorisation requests and subsequent reviews to a unique individual. Additional capability will be developed to assist with in-hospital management of immunoglobulin products, integrated with BloodNet and existing Laboratory Information Systems (LIS) interfaces, along with details of infusion plans, review cycles and capturing of clinical outcomes.

17. Will an approved authorisation request still trigger product being sent to the hospital for the patient's initial treatment?

Current arrangements will continue during the transition period and where this currently occurs it will be unchanged from 5 November. However, the Australian Red Cross Blood Service will assist facilities to move towards coordinated in-hospital product ordering and management, where an order for product will need to be submitted to the Dispenser (blood bank, pathology laboratory, pharmacy, private pathology or other delegate), following patient authorisation. The Dispenser will then be required to order the product from the Australian Red Cross Blood Service.

18. Does the Prescriber need to inform the nominated Dispenser of patient authorisation?

The Dispenser should be advised of patient authorisation, including product type, dosage, frequency and the review date, to assist with product ordering and management.

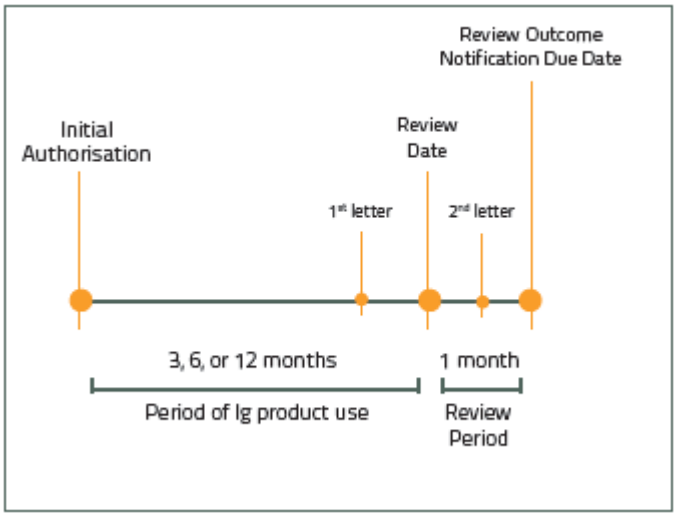
19. What do I do if my patient does not receive their planned infusion?

The Australian Red Cross Blood Service should be notified that the patient did not receive their planned infusion so that they can update the records and re-allocate the product to another patient.

20. When are the patient treatment review outcomes required?

The current requirement which applies for many conditions, for a review form or similar correspondence to be submitted to the Australian Red Cross Blood Service in order to receive continued supply of funded product, is unchanged.

Patient treatment review outcomes are due to be provided to the Authoriser within one month of the patient review date for continuing access and supply of government funded product.



21. What will happen if the patient treatment review outcomes are not provided within the required timeframe?

As specified in the *Criteria for the clinical use of intravenous immunoglobulin in Australia* 2012, immunoglobulin products should only be continued where there is a demonstrated clinical benefit, and access to the continuing supply of product will cease where clinical benefit cannot be demonstrated as required.

If a Prescriber is aware that there may be a problem in providing patient treatment review outcomes within the required timeframe, they should contact their normal Australian Red Cross Blood Service or other delegated Authoriser as early as possible.

22. Who received communication packs regarding strengthened immunoglobulin authorisation and management?

Current Prescribers, Dispensers, infusion clinic Nurses and hospital management have received a communication pack via direct mail out.

All information is available on the NBA website, [www.blood.gov.au/immunoglobulin-ig-governance-program.](www.blood.gov.au/immunoglobulin-ig-governance-program)

23. What is the Ig System and why is it being developed?

The Ig System is a national immunoglobulin product authorisation and outcomes database. It is being developed to support the Ig Governance National Policy and *Criteria for the clinical use of intravenous immunoglobulin in Australia 2012 (Criteria),* enabling Authorisation Requests to be submitted electronically and work-flowed to the Authoriser for assessment and approval. Improved national data will enhance the ability to further develop the Criteria and provide an improved evidence base for practice improvement and research.

24. When is the Ig System being implemented?

The Ig System is currently in development and due to be implemented in early 2016.

25. How can I get involved in the Ig System development?

User Reference Groups are being established for Prescribers, Dispensers, Nurses and Authorisers. If you would like to be involved you can contact the Ig System Development Project team via IgGovernance@blood.gov.au or call 13 000 44 468 (13 000 IG GOV).

26. When a patient does not attend for their infusion, the Australian Red Cross Blood Service is notified so they can update their records and allocate the product to another patient. How is this going to be managed in the Ig System?

The Ig System will include a Patient Registry to enable the association of authorisation requests and subsequent reviews to a unique individual. Additional capability will be developed to assist with in hospital management of immunoglobulin products, integrated with BloodNet and existing LIS interfaces, along with details of infusion plans, review cycles and capturing of clinical outcomes. Until the Ig System is implemented, current arrangements for notification of non-dispensing should continue.