

IMMUNOGLOBULIN PRODUCTS IN AUSTRALIA: INFORMATION ABOUT ACCESS AND CONSENT

There is growing demand for immunoglobulin products around the world – the number of severe, chronic, and life-threatening conditions they are used to treat is expanding. For many people with these conditions, they are an essential and life-saving therapy.

Why is national governance of immunoglobulin products needed?

Blood plasma donations from thousands of healthy people are needed to make immunoglobulin products. Each litre of plasma (the fluid part of blood containing immunoglobulins) donated produces only a tiny amount of immunoglobulin – not even enough for one adult dose.

Complex manufacturing processes safeguard the purity of the final products, making them safe to use, but expensive to produce.

This means immunoglobulin products are a precious and valuable resource. Careful management is needed to ensure that there is an adequate, secure and affordable supply of immunoglobulin products for Australians who need them.

How does national governance work?

Management of the supply of immunoglobulin products and services across Australia is the responsibility of the National Blood Authority (NBA). The NBA looks at the demand for immunoglobulin products to determine how much is needed, how it is supplied, and which manufacturers supply it. The NBA considers product quality, safety, security of supply and value for money, as immunoglobulin products are very costly.

The NBA is also responsible for promoting the safe and effective use of immunoglobulin products. This is achieved using strategies and programs to improve how immunoglobulin products are used.

To support these two key responsibilities of managing supply and administering proper use, the National Immunoglobulin Governance Program was developed by the NBA. The NBA manages the Program on behalf of all states and territories.

The Program has three main parts: the National Policy, BloodSTAR, and the Criteria for the Clinical Use of Immunoglobulin in Australia (known as the Criteria).

Together, they make up a framework of clear policies and procedures detailing how immunoglobulin products are accessed and approved, and the reporting and monitoring requirements that health professionals must follow when they are used. This ensures that an affordable and sustainable supply of immunoglobulin products can be achieved.

What are the Criteria for the Clinical Use of Immunoglobulins?

The conditions and circumstances under which government funded immunoglobulin products can be considered for use are set out in the **Criteria for the Clinical Use of Immunoglobulin in Australia (The Criteria)**.

The Criteria:

- ✓ list the conditions where evidence suggests that a person is most likely to benefit from immunoglobulin therapy
- ✓ set out the eligibility criteria for access to immunoglobulins – for example, how severe the condition is
- ✓ set out the criteria for the review of a person's response to immunoglobulin treatment (see What is treatment review?)

What is BloodSTAR?

BloodSTAR (Blood System for Tracking Authorisations and Reviews) is an online system used by medical officers and those responsible for authorising the use of immunoglobulin products, reviewing product use for the treatment of conditions listed in the Criteria, and managing access to products.

Providing your consent – what does it mean?

You will be asked to provide consent for two reasons.

You will be asked to sign a *Record of Privacy Consent* form, or state your consent to have your personal information stored in BloodSTAR.

In order to request government funded Ig your medical officer will need to enter your details in BloodSTAR. This includes identification details, such as your name, and information about your condition. The main purpose of collecting your information is to correctly identify you and to assess your eligibility to receive these products.

You can choose not to provide consent. However, your doctor will not be able to submit your personal information to enable assessment of your eligibility and as a result you will not be able to receive government-funded immunoglobulin products.

You will be asked to sign an *informed consent* form (Carers will be asked to sign a different consent form) when you attend hospital for immunoglobulin products. At this time, your health professional will explain to you:

- ▶ the reason that you need immunoglobulin treatment
- ▶ the risks and benefits of the treatment, including any side effects
- ▶ what can happen if you don't have treatment.

Consent for people receiving regular intravenous immunoglobulin is valid for a limited period of time, usually for 12 months. You will need to renew your consent if you have ongoing treatment.

What is treatment review? Why is it important?

Once you have started immunoglobulins, your response to treatment is assessed to find out how your condition is progressing ('clinical benefit'). This might be at 3, 6 or 12 months, depending on your condition. Evidence of clinical benefit is a requirement for ongoing access to government-funded immunoglobulin.

Measuring clinical benefit is different for every condition. Your doctor will consider things such as:

- ▶ improvement in the signs and symptoms of your condition. For example:
 - If you are having treatment for an immune deficiency, are you still having infections? Have you needed antibiotics?
- ▶ if you are having treatment for an autoimmune condition, have you had improvements in weakness or fatigue?
- ▶ whether your condition is still active. If not, immunoglobulin treatment may no longer be necessary for your day-to-day health
- ▶ if you have developed a side effect from treatment.

It is also possible that the Criteria for treating your condition might have changed.

Any of these things can affect decisions about your treatment and the best way to manage your condition. Most people with primary immune deficiencies need immunoglobulin products for life, but treatment review is still important – for example, your dose may need to be changed. For other people, immunoglobulin products may no longer be helpful, and can even cause harm in rare cases.

There may be changes to your treatment

Following treatment review:

- ▶ your immunoglobulin product may be switched to a different brand or form that is easier to use or has fewer side effects
- ▶ your immunoglobulin dose might be reduced or given less often
- ▶ your immunoglobulin might be stopped, and replaced with other more suitable treatment for your condition. For some conditions, such as immune deficiencies, this might not apply.

The reasons for any changes will be explained to you. Ask your health professionals for more information if you have any concerns. They can help you manage changes to your treatment so that your health and quality of life are maintained as much as possible.

Treatment reviews are an important step in your patient journey

- ▶ the research tells us that every person will respond differently to immunoglobulins and that treatment should be based on the needs of each person.
Treatment reviews are practical and safe ways to address this and to make sure you are achieving your treatment goals, as advised by your doctor. Changes to your treatment may even lead to health benefits such as fewer side effects.
- ▶ it is important to make sure you attend review appointments as planned, even if you are feeling well. You will still need a regular review to monitor your progress and make sure your access to immunoglobulin continues as needed.

Preparing for treatment review

- ▶ use a treatment diary or keep a record of any changes to your health since your last appointment. This might include infections or symptoms such as fatigue. Remember to take it with you whenever you visit your doctor or other health professionals. This can help them develop a more effective treatment plan.
- ▶ prepare a list of any questions you have to ask your doctor or other health professionals at your review. These might be about how your response to treatment is measured as this will be different for every condition.
- ▶ schedule your next appointment when you leave and make a record of the date and time.

Want to know more?

You can find out more about immunoglobulin here:

- ▶ National Blood Authority: Immunoglobulin: www.blood.gov.au/lg
 - ▶ National Blood Authority: Patient factsheets and resources www.blood.gov.au/patient-factsheets-and-resources
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VALUE IN PRESCRIBING PROGRAM – IMMUNOGLOBULIN PRODUCTS

Increasing the awareness and understanding amongst health professionals of access to immunoglobulin products in Australia, and improving health outcomes for patients through access to better health information to manage their health conditions. Funded by the Australian Government Department of Health through the Value in Prescribing Program: Immunoglobulins Products Grant.

